

**SALLY HANSEN OUCH-RELIEF STRIPLESS HARD 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.

Sally Hansen Ouch-Relief Stripless Hard Wax Kit

(Ouch-Relief™ Numbing Wipe)

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 raws 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 - Sally Hansen Ouch-Relief Stripless Hard Wax Kit Label

OUCH-RELIEF™ STRIPLESS HARD WAX KIT

PAIN-
RELIEF
TECHNOLOGY™

Sally Hansen ®

FOR FACE & BODY

Pre-Treatment Helps
Reduce Pain While
Waxing

Results Last Up to
8 Weeks!*

Body Contouring
Formula Eliminates
Coarse Hair

*Individual hair re-growth results may vary

Wax NET WT. 4.0 oz 113 g,

3 Ouch-Relief™ Numbing Wipes,
6 Spatulas, 4 Azulene Oil Finish Wipes,
Instructions

Dermatologist & Salon Tested



SALLY HANSEN OUCH-RELIEF STRIPLESS HARD WAX KIT

benzocaine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66184-161
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-161-01	1 in 1 CARTON; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 APPLICATOR	3
Part 2	1 PACKET	4
Part 3	1 JAR	113.4 g

Part 1 of 3

OUCH-RELIEF NUMBING WIPE

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	6 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-163-01	3 in 1 PACKET		
1		1 in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/18/2018	

Part 2 of 3

AZULENE OIL FINISHING WIPE

other skin care preparations

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	MINERAL OIL (UNII: T5L8T28FGP)	
INGR	ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
INGR	WHEAT GERM OIL (UNII: 14C97E680P)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	GUAIAZULENE (UNII: 2OZ1K9JKQC)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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		10/18/2018	

Part 3 of 3

WAX

other skin care preparations

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	GLYCERYL ROSINATE (UNII: SD112V492J)	
INGR	PARAFFIN (UNII: I9O0E3H2ZE)	
INGR	YELLOW WAX (UNII: 2ZA36H0S2V)	
INGR	POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	MICA (UNII: V8A1AW0880)	
INGR	OAT KERNEL OIL (UNII: 3UVP41R77R)	
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	

INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	GERANIOL (UNII: L837108USY)	
INGR	.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
INGR	BENZYL BENZOATE (UNII: N863NB338G)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
INGR	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		113.4 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		10/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/18/2018	

Labeler - Coty US LLC (039056361)

Establishment

Name	Address	ID/FEI	Business Operations
Crystal Claire Cosmetics Inc.		205493484	manufacture(66184-161)

Revised: 7/2023

Coty US LLC