

## SUCTION TOOTHBRUSHES- cetylpyridinium chloride

Sage Products 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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### Suction Toothbrushes

#### *Drug Facts*

<i>Active Ingredient</i>	<i>Purpose</i>
<b>Antiseptic Oral Rinse</b> .05% Cetylpyridinium chloride	Oral Antiseptic

#### *Uses*

- Helps reduce the chance of infection in minor oral irritation.
- Aids in the removal of debris, dental plaque and secretions.

#### *Warnings*

##### **Stop use and ask a doctor if:**

- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

##### **Keep out of reach of children.**

If more than used for antiseptis is accidentally swallowed, get medical help or contact a Poison Control Center right away.

#### *Directions*

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove toothbrush and attach to suction line.
- Clean teeth and oral cavity for approximately one minute.
- To suction, place thumb over port.
- Repeat cleaning with other toothbrush as needed.
- Discard after use.
- Apply Mouth Moisturizer as needed.
- Use up to 4 times daily, or as directed by a dentist or doctor.
- Children under 12 years of age should be supervised in the use of this product.
- Children under 3 years of age, consult a dentist or doctor.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

#### *Inactive Ingredients*

Water, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, FD&C Blue #1.

### Questions

Call toll free 800-323-2220

### Suction Toothbrushes

**PEEL HERE**

**TOOTHETTE<sup>®</sup>**  
*Oral Care*

**SUCTION TOOTHBRUSHES**  
With Antiseptic Oral Rinse  
and Mouth Moisturizer

For healthcare professional, single use only

**CONTENTS:** 2 Suction Toothbrushes with sodium bicarbonate  
0.25 fl. oz./7ml Antiseptic Oral Rinse  
0.07 oz./2g Mouth Moisturizer

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***Sodium Bicarbonate ingredients\****: Water, sodium bicarbonate, sodium carboxymethyl cellulose, sodium lauryl sulfate, flavor, sodium saccharin, sodium benzoate.

***Mouth Moisturizer ingredients\****: Water, coconut oil, xylitol, spearmint flavor, sodium carboxymethyl cellulose, tocopheryl acetate (vitamin E), spearmint oil, carbomer, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.

\* Manufactured for Sage Products LLC

NOT MADE WITH NATURAL RUBBER LATEX  
MADE IN U.S.A.

Reorder #6173

**SAGE**<sup>®</sup>  
PRODUCTS

Sage Products LLC

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Patents: [www.sageproducts.com/patents](http://www.sageproducts.com/patents)



## Antiseptic Oral Rinse

**Antiseptic Oral Rinse**  
Active Ingredient:  
Cetylpyridinium chloride 0,05%

**Squeeze Here**

**To Release Fluid**

**BURST PACKET BEFORE OPENING OUTER PACKAGE**  
Do not remove from package  
0,25 fl. oz./7 mL

R5267C

**LOT**

## SUCTION TOOTHBRUSHES

cetylpyridinium chloride kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53462-273
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-273-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2006	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	7 mL
Part 2	1 PACKET	2 g
Part 3		1

**Part 1 of 3****ANTISEPTIC ORAL RINSE**

cetylpyridinium chloride mouthwash

**Product Information**

<b>Item Code (Source)</b>	NDC:53462-175
<b>Route of Administration</b>	BUCCAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PEPPERMINT (UNII: V95R5KMY2B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1		1 in 1 KIT		
1	NDC:53462-175-60	7 mL 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 not final	part356	06/21/2000	

## Part 2 of 3

### MOUTH MOISTURIZER

other oral hygiene products

## Product Information

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	XYLITOL (UNII: VCQ006KQ1E)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
INGR	SPEARMINT OIL (UNII: C3M81465G5)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 KIT		
1		2 g 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			

## Part 3 of 3

# SODIUM BICARBONATE

other oral hygiene products

## Product Information

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/30/2006	

**Labeler** - Sage Products LLC (054326178)

**Registrant** - Sage Products LLC (054326178)