

QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q4- cetylpyridinium chloride and hydrogen peroxide
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.

QCare Oral Cleansing and Suctioning System, Q4

Drug Facts

Suction Swab with Perox-A-Mint® Solution

Active Ingredient	Purpose
PEROX-A-MINT	
Hydrogen peroxide 1.5%	Oral debriding agent

Use

- Aids in the removal of secretions and debris.

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 the reach of children.

If more than used for debriding 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 Mouth Moisturizer and Applicator Swab.
- Attach Suction Swab to suction line.
- Clean teeth and oral cavity for approximately one minute.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach Covered Yankauer to suction line.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.
- Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age: supervise use.
- 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, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985)

Drug Facts

Suction Toothbrush with Antiplaque Solution

<i>Active Ingredient</i>	<i>Purpose</i>
ANTIPLAQUE Cetylpyridinium chloride .05%	Antigingivitis/antiplaque

Uses

Suction Toothbrush with Antiplaque Solution:

- Aids in the removal and prevention of plaque that leads to gingivitis.

Oropharyngeal Suction Catheter packages:

- Aids in the removal of secretions from the oropharyngeal cavity only.

Warnings

Stop use and ask a dentist if:

- Gingivitis, bleeding or redness persists for more than 2 weeks.
- You have painful or swollen gums, pus from the gum line, loose teeth or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of the reach of children under 6 years of age.

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

Directions

Suction Toothbrush with Antiplaque Solution:

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove Mouth Moisturizer and Applicator Swab.
- Attach Toothbrush to suction line.
- Clean teeth and oral cavity for approximately one minute.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Toothbrush. Reattach Covered Yankauer to suction line.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.
- Adults and children 12 years of age and older: use two times daily or as directed by a dentist. Do not swallow the solution.
- Children ages 6 to 12 years: supervise use.
- Children under 6 years of age: do not use.
- 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.

Oropharyngeal Suction Catheter:

- Peel lid to open.
- Attach Suction Catheter to suction line.
- Suction secretions from the oropharyngeal cavity.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Catheter. Reattach Covered Yankauer to suction line.
- Use bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.

Caution

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or licensed practitioner.

Inactive Ingredients**Suction Toothbrush with Antiplaque Solution:**

Water, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, Blue 1 (CI42090).

Questions?

Call toll-free 800-323-2220

Manufactured for Sage Products, LLC Cary, IL

NOT MADE WITH NATURAL RUBBER LATEX. FOR SINGLE USE ONLY. MADE IN U.S.A.

QCare Oral Cleansing & Suctioning System, q4 Reorder#6424



**Perox-A-Mint®
Solution**

Active Ingredient:
Hydrogen
peroxide 1.5%

Squeeze Here



To Release Fluid

**BURST PACKET
BEFORE OPENING
OUTER PACKAGE**

Do not remove
from package

0.25 fl. oz./7 mL

R5266C



**Perox-A-Mint®
Solution**

Active Ingredient:
Hydrogen
peroxide 1.5%

Squeeze Here



To Release Fluid

**BURST PACKET
BEFORE OPENING
OUTER PACKAGE**

Do not remove
from package

0.25 fl. oz./7 mL



LOT



Antiplaque Solution

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

R5269C



Antiplaque Solution

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



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Tear Here

Q-Care[®]

q4[°]

Oral Cleansing & Suctioning System

Setup Instructions: Multi-Port Canister

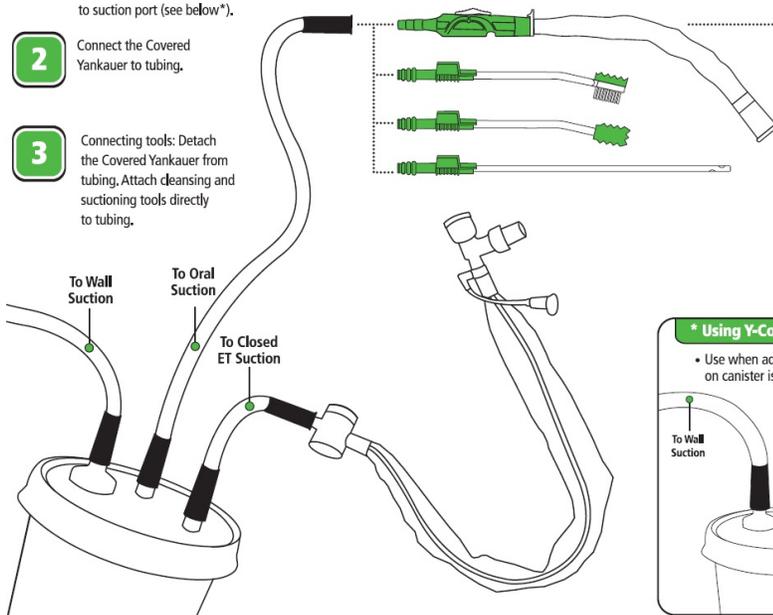
1 Connect tubing to suction port on canister. If additional port is needed, attach Y-Connector to suction port (see below*).

2 Connect the Covered Yankauer to tubing.

3 Connecting tools: Detach the Covered Yankauer from tubing. Attach cleansing and suctioning tools directly to tubing.

Cleansing and Suctioning Tools attach directly to standard suction lines.

Using the Covered Yankauer to aid with removal of secretions:



- Follow hospital protocol.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Retract sleeve until cap locks in place.
- To suction, move switch to ON. When finished, move switch to OFF to prevent loss of suction power.
- Rinse after use until tubing is clear.
- Between uses, pull sleeve over tip to cover.
- Discard Yankauer and Y-Connector (if used) after using for 24 hours, or according to hospital protocol.
- For single patient oral use.

* Using Y-Connector

- Use when additional suction port on canister is needed.



IMPORTANT: Both ports on Y-Connector must be utilized or a loss of suction power can occur.

Contents:

- 1 Covered Yankauer and Y-Connector
- 2 Suction Toothbrush packages with Antiplaque solution
- 4 Suction Oral Swab packages with Perox-A-Mint[®] solution
- 2 Oropharyngeal Suction Catheter packages

Ingredients:

Antiplaque solution active ingredient: Cetylpyridinium chloride 0.05%
 Perox-A-Mint[®] solution active ingredient: Hydrogen peroxide 1.5%
 Kit also contains sodium bicarbonate and Mouth Moisturizer. For detailed listing of ingredients, see the enclosed individual packages.

Caution:

Federal (U.S.A.) law restricts this device (kit) to sale by or on the order of a physician or licensed practitioner.

Non-sterile • Not made with natural rubber latex

Reorder # 6424



SAGE[®]

PRODUCTS INC.

Sage Products LLC

3909 Three Oaks Road | Cary, Illinois 60013
 www.sageproducts.com | 800-323-2220



MADE IN U.S.A.
 Patents: www.sageproducts.com/patents

R4679B

START TIME AND DATE: _____
 Patient ID: _____
 Nurse Initials: _____

TOOTHETTE[®]
 Oral Care

Q-Care[®] **q4[°]**
 Oral Cleansing & Suctioning System

Reorder # 6424



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 PRODUCTS INC.

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 Cary, Illinois 60013
 www.sageproducts.com
 800-323-2220

Step 6 Suction Swab



Cleans oral cavity and helps remove secretions which may lead to oropharyngeal colonization.

Step 5 Suction Swab



Cleans oral cavity and helps remove secretions which may lead to oropharyngeal colonization.

Step 4 Suction Toothbrush



Helps remove dental plaque, a key risk factor for HAP/VAP.

Suction Catheter



Helps remove secretions from the oropharyngeal cavity, a key risk factor for HAP/VAP.

START TIME AND DATE: _____
Patient ID: _____
Nurse Initials: _____



Q-Care® q4°
Oral Cleansing & Suctioning System

Reorder # 6424



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Cary, Illinois 60013
www.sageproducts.com
800-323-2220

Step 3 Suction Swab



Cleans oral cavity and helps remove secretions which may lead to oropharyngeal colonization.

Step 2 Suction Swab



Cleans oral cavity and helps remove secretions which may lead to oropharyngeal colonization.

Step 1 Suction Toothbrush



Helps remove dental plaque, a key risk factor for HAP/VAP.

Suction Catheter



Helps remove secretions from the oropharyngeal cavity, a key risk factor for HAP/VAP.

Kil Bar Code:



Patent Pending

TOOTHETTE[®] Oral Care Suction Swab with Perox-A-Mint[®] Solution

CONTENTS: 1 Suction Swab with sodium bicarbonate, .25 fl. oz./7ml Perox-A-Mint Solution, 0.07 oz./2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts	
Active ingredient	Purpose
PEROX-A-MINT [®] : Hydrogen peroxide 1.5%.....	Oral debriding agent
Uses	
• Aids in the removal of secretions and debris.	
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 debriding 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 Mouth Moisturizer and Applicator Swab.	
• Attach Suction Swab to suction line.	
• Clean teeth and oral cavity for approximately one minute.	
• To suction, place thumb over port.	
• To clear tubing, rinse with sterile saline or appropriate solution.	
• Discard Suction Swab, Reattach Covered Yankauer to suction line.	
• Place Mouth Moisturizer on Applicator Swab.	
• Apply as needed to lips and inside mouth.	
• Use up to 4 times daily or as directed by a dentist or doctor.	
• Children under 12 years of age: supervise use.	
• 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, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).	
Questions? Call toll-free 800-323-2220.	

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, carbones, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.
* Manufactured for Sage Products, Inc. • Cary, IL
Covered under one or more of the following patents: 5,085,633; 5,151,094; 5,378,226

LATEX FREE • FOR SINGLE USE ONLY • MADE IN U.S.A.



Oral Check[®] Scan bar code for compliance to protocol

TOOTHETTE[®] Oral Care Suction Swab with Perox-A-Mint[®] Solution

CONTENTS: 1 Suction Swab with sodium bicarbonate .25 fl. oz./7ml Perox-A-Mint Solution, 0.07 oz./2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts	
Active ingredient	Purpose
PEROX-A-MINT [®] : Hydrogen peroxide 1.5%.....	Oral debriding agent
Uses	
• Aids in the removal of secretions and debris.	
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 debriding 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 Mouth Moisturizer and Applicator Swab.	
• Attach Suction Swab to suction line.	
• Clean teeth and oral cavity for approximately one minute.	
• To suction, place thumb over port.	
• To clear tubing, rinse with sterile saline or appropriate solution.	
• Discard Suction Swab, Reattach Covered Yankauer to suction line.	
• Place Mouth Moisturizer on Applicator Swab.	
• Apply as needed to lips and inside mouth.	
• Use up to 4 times daily or as directed by a dentist or doctor.	
• Children under 12 years of age: supervise use.	
• 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, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985).	
Questions? Call toll-free 800-323-2220.	

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, carbones, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.
* Manufactured for Sage Products, Inc. • Cary, IL
Covered under one or more of the following patents: 5,085,633; 5,151,094; 5,378,226

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Oral Check[®] Scan bar code for compliance to protocol

TOOTHETTE[®] Oral Care Suction Toothbrush with Antiplaque Solution

CONTENTS: 1 Suction Toothbrush with sodium bicarbonate .25 fl. oz./7ml Antiplaque Solution, 0.07 oz./2g Mouth Moisturizer, 1 Applicator Swab

Drug Facts	
Active ingredient	Purpose
ANTIPLAQUE [®] : Cetylpyridinium chloride .05%.....	Antigingivitis/antiplaque
Uses	
• Aids in the removal and prevention of plaque that leads to gingivitis.	
Warnings	
Stop use and ask a dentist if:	
• Gingivitis, bleeding or redness persists for more than 2 weeks.	
• You have painful or swollen gums, pus from the gum line, loose teeth or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.	
Keep out of reach of children under 6 years of age.	
If more than used for brushing 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 Mouth Moisturizer and Applicator Swab.	
• Attach Toothbrush to suction line.	
• Clean teeth and oral cavity for approximately one minute.	
• To suction, place thumb over port.	
• To clear tubing, rinse with sterile saline or appropriate solution.	
• Discard Toothbrush, Reattach Covered Yankauer to suction line.	
• Place Mouth Moisturizer on Applicator Swab.	
• Apply as needed to lips and inside mouth.	
• Adults and children 12 years of age and older: use two times daily or as directed by a dentist. Do not swallow the solution.	
• Children ages 6 to 12 years: supervise use.	
• Children under 6 years of age: do not use.	
• 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, Blue 1 (CI 42090).	
Questions? Call toll-free 800-323-2220.	

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, carbones, polysorbate 20, polysorbate 80, potassium sorbate, cetylpyridinium chloride.
* Manufactured for Sage Products, Inc. • Cary, IL
U.S. Patent No. 6,238,213

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Oral Check[®] Scan bar code for compliance to protocol

TOOTHETTE[®] Oral Care Oropharyngeal Suction Catheter Non-sterile

CONTENTS: 1 Suction Catheter

- Uses**
- Aids in the removal of secretions from the oropharyngeal cavity only.
- Directions**
- Peel lid to open.
 - Attach Suction Catheter to suction line.
 - Suction secretions from the oropharyngeal cavity.
 - To suction, place thumb over port.
 - To clear tubing, rinse with sterile saline or appropriate solution.
 - Discard Suction Catheter, Reattach Covered Yankauer to suction line.
 - Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Caution**
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or licensed practitioner.

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MADE IN U.S.A.



QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q4 cetylpyridinium chloride and hydrogen peroxide kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53462-424

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-424-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2008	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 PACKET	28 mL
Part 2	2 PACKET	14 mL
Part 3	6 PACKET	12 g
Part 4		1

Part 1 of 4**PEROX-A-MINT SOLUTION**

hydrogen peroxide mouthwash

Product Information

Item Code (Source)	NDC:53462-075
Route of Administration	BUCCAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 KIT		
1	NDC:53462-075-60	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	05/21/1998	

Part 2 of 4

ANTIPLAQUE SOLUTION

cetylpyridinium chloride mouthwash

Product Information

Item Code (Source)	NDC:53462-275
Route of Administration	BUCCAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	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: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 KIT		
1	NDC:53462-275-60	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	01/09/2009	

Part 3 of 4

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	SPEARMINT OIL (UNII: C3M81465G5)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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 4 of 4

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: 059QF0KO0R)	
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	06/30/2008	

Labeler - Sage Products, LLC (054326178)

Revised: 6/2018

Sage Products, LLC