

QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q4- cetylpyridinium chloride and hydrogen peroxide
QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q8- 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

Drug Facts

Active Ingredient: PEROX-A-MINT: Hydrogen Peroxide 1.5%	Purpose Oral Debriding Agent
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Active Ingredient: ANTIPLAQUE*: Cetylpyridinium chloride .05%	Purpose Antigingivitis/antiplaque
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USES

Suction Swab with Perox-A-Mint:

Aids in the removal of secretions and debris.

Suction Toothbrush with Antiplaque Solution:

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

Oropharyngeal Suction Catheter:

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

WARNINGS

Suction Swab with Perox-A-Mint Solution:

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.

Suction Toothbrush with Antiplaque Solution:

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.

Suction Swab with Perox-A-Mint Solution:**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.

Suction Toothbrush with Antiplaque Solution:**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**Suction Swab with Perox-A-Mint Solution:**

- **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 Handle.
- Clean teeth and oral cavity for approximately one minute.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Swab. Reattach Covered Yankauer to Suction Handle.
- 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.

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 Handle.
- Clean teeth and oral cavity for approximately one minute.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Toothbrush. Reattach Covered Yankauer to Suction Handle.
- 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 Handle.
- Suction secretions from the oropharyngeal cavity.
- To suction, slide switch to ON. When finished, return switch to OFF.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Suction Catheter. Reattach Covered Yankauer to Suction Handle.
- 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.

Inactive Ingredients**Suction Swab with Perox-A-Mint Solution:**

Water, menthol flavor, polysorbate 80, phosphoric acid, sodium saccharin, Blue 1 (CI 42090), Yellow 6 (CI 15985)

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 and Suctioning System, Q4

Tear Here

Q-Care®

q4°

Oral Cleansing & Suctioning System

Setup Instructions: Multi-Port Canister

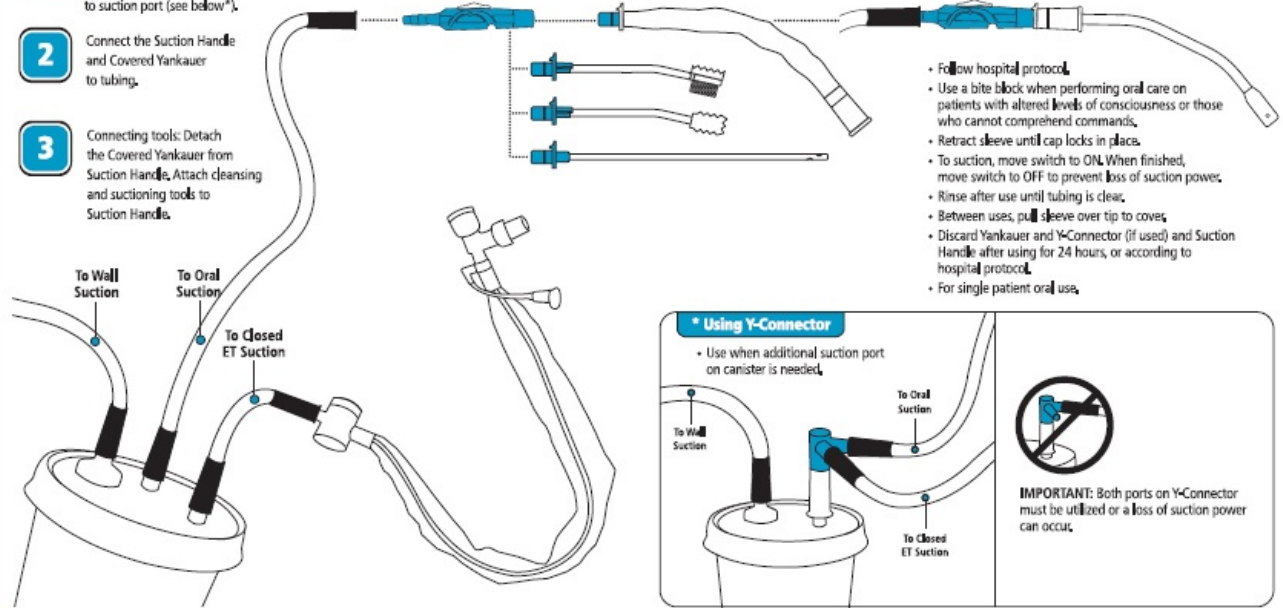
1 Connect tubing to suction port on canister. If additional port is needed, attach Y-Connector to suction port (see below).

2 Connect the Suction Handle and Covered Yankauer to tubing.

3 Connecting tools: Detach the Covered Yankauer from Suction Handle. Attach cleansing and suctioning tools to Suction Handle.

Cleansing and Suctioning Tools attach to Suction Handle.

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) and Suction Handle 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, Suction Handle 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 #6804



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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

START TIME _____
AND DATE: _____

Patient ID: _____

Nurse Initials: _____

TOOTHETRE®

Oral Care

Q-Care®

q4°

Oral Cleansing & Suctioning System

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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/VAR.

Suction Catheter



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

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



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Oral Cleansing & Suctioning System

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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/VAR.

Suction Catheter



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

Tear Here

Q-Care®

q8°

Oral Cleansing & Suctioning System

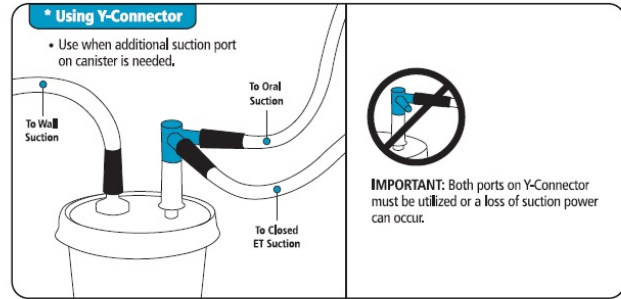
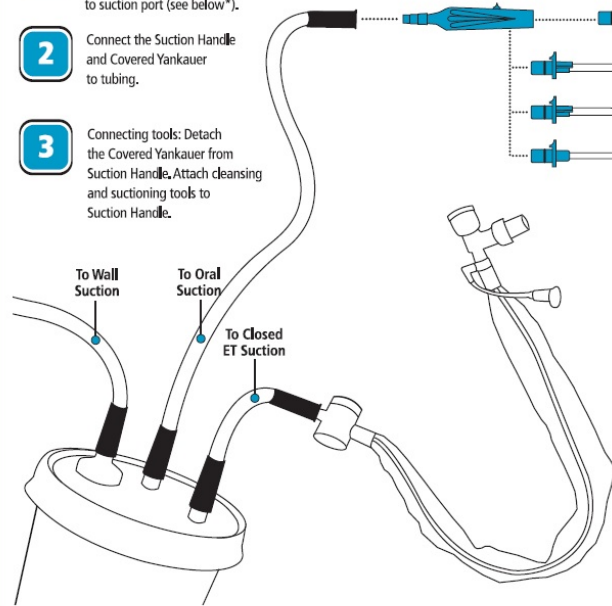
Setup Instructions: Multi-Port Canister

- 1 Connect tubing to suction port on canister. If additional port is needed, attach Y-Connector to suction port (see below*).
- 2 Connect the Suction Handle and Covered Yankauer to tubing.
- 3 Connecting tools: Detach the Covered Yankauer from Suction Handle. Attach cleansing and suctioning tools to Suction Handle.

Cleansing and Suctioning Tools attach to Suction Handle.

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) and Suction Handle after using for 24 hours, or according to hospital protocol.
- For single patient oral use,



Contents:

- 1 Covered Yankauer, Suction Handle and Y-Connector
- 2 Suction Toothbrush packages with Antiplaque solution
- 1 Suction Oral Swab package with Perox-A-Mint® solution
- 1 Oropharyngeal Suction Catheter package

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:

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

TOOTHHERE®
Oral Care

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Oral Cleansing & Suctioning System

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Step 3 Suction Toothbrush



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

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.

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



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Oral Cleansing & Suctioning System

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Step 3

Suction Toothbrush



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

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.



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

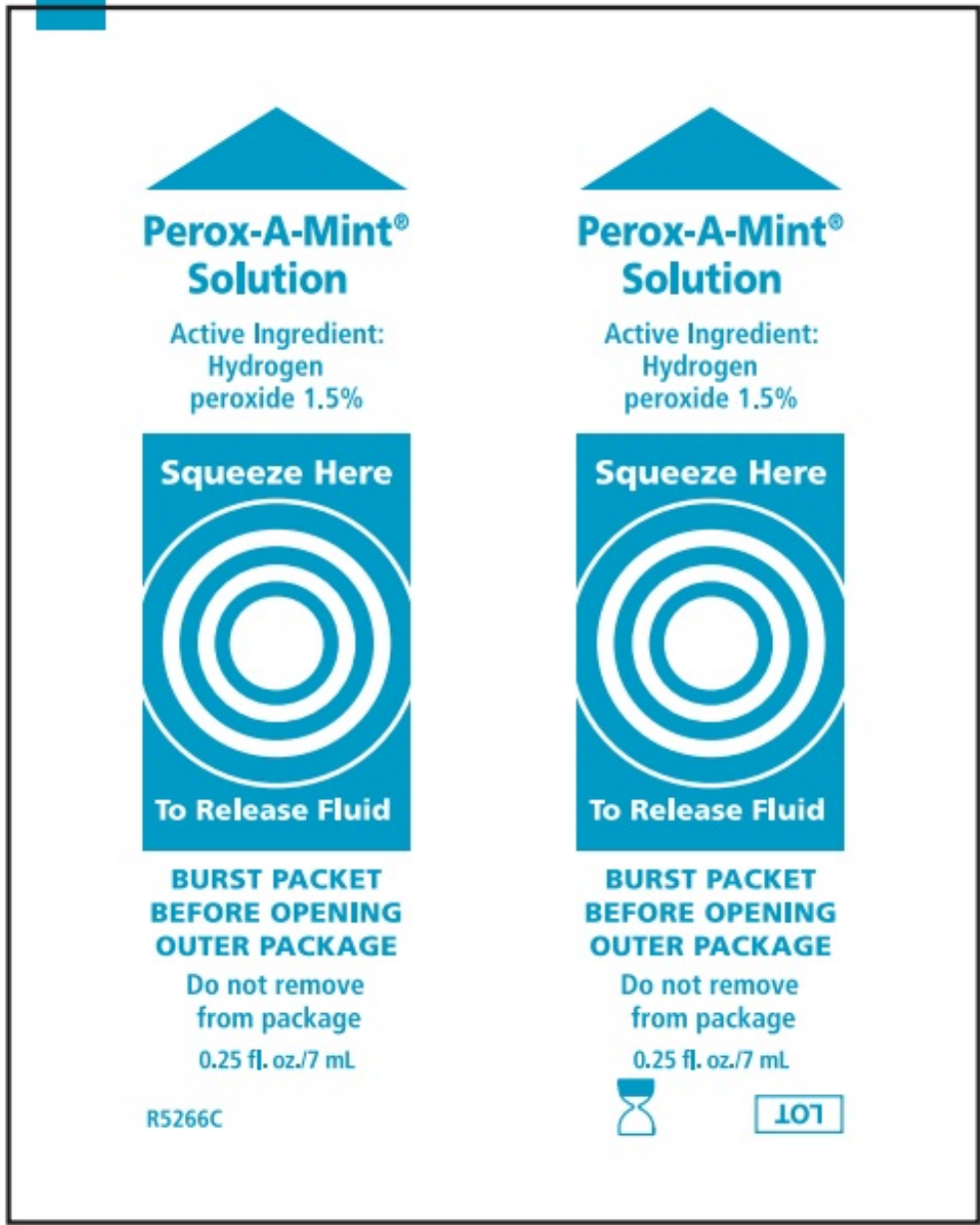
**BURST PACKET
BEFORE OPENING
OUTER PACKAGE**

Do not remove
from package

0.25 fl. oz./7 mL



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QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q4

cetylpyridinium chloride and hydrogen peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-804
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-804-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2004	

Quantity of Parts

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

Part 1 of 4

PEROX-A-MINT SOLUTION

hydrogen peroxide mouthwash

Product Information

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: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 KIT		
1		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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 KIT		
1		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 3 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			

Part 4 of 4

MOUTH MOISTURIZER

other oral hygiene products

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
INGR	CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
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)	

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			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/30/2004	

QCARE ORAL CLEANSING AND SUCTIONING SYSTEM, Q8

cetylpyridinium chloride and hydrogen peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-808
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-808-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/30/2004	04/09/2018

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	7 mL
Part 2	2 PACKET	14 mL
Part 3		1
Part 4	3 PACKET	6 g

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: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 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
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3)	CETYLPIRIDINIUM CHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

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

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	05/21/1998	

Part 3 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			

Part 4 of 4

MOUTH MOISTURIZER

other oral hygiene products

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
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: HHT01Z NK31)	
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3 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			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/30/2004	04/17/2018

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Revised: 2/2022

Sage Products LLC