

SUCTION SWABS WITH PEROX-A-MINT SOLUTION- 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.

Suction Swabs with Perox-A-Mint® Solution

Drug Facts

Suction Swab with Perox-A-Mint Solution

Active Ingredient:	Purpose
PEROX-A-MINT: Hydrogen Peroxide 1.5%	Oral Debriding Agent

Uses

- Aids in the removal of debris 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 debriding is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Suction Swabs with Perox-A-Mint solution and Mouth Moisturizer

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove Suction Swab and attach to suction line.
- Clean teeth and oral cavity for approximately 1 minute.
- To suction, place thumb over port.
- Repeat cleaning with other Suction Swab as needed.
- To clear tubing, rinse with sterile saline or appropriate solution.
- 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: 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 Swabs with Perox-A-Mint solution

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove Suction Swab and attach to suction line.
- Clean teeth and oral cavity for approximately 1 minute.
- To suction, place thumb over port.
- Repeat cleaning with other Suction Swab as needed.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard after use.
- 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**.

Suction Swabs with Perox-A-Mint Solution

▲ **PEEL HERE** ▲

NPN 02242225

TOOTHETTE[®]

Oral Care

SUCTION SWABS

with Perox-A-Mint[®] solution
and Mouth Moisturizer

For single use only

CONTENTS: 2 Suction Swabs with sodium bicarbonate
0.25 fl. oz./7ml. Perox-A-Mint solution
0.07 oz./2g Mouth Moisturizer

Pour la version française, consulter le feuillet ci-inclus

<i>Drug Facts</i>	
<i>Active ingredient</i>	<i>Purpose</i>
PEROX-A-MINT SOLUTION*:	
Hydrogen peroxide 1.5%	Oral Debriding Agent
<i>Uses</i>	
• Aids in the removal of debris and secretions.	
<i>Warnings</i>	
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 Suction Swab and attach to suction line.
 - Clean teeth and oral cavity for approximately 1 minute.
 - To suction, place thumb over port.
 - Repeat cleaning with other Suction Swab as needed.
 - To clear tubing, rinse with sterile saline or appropriate solution.
 - 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: 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, cocos nucifera (coconut) oil, xylitol, mentha viridis (spearmint) flavor (aroma), sodium carboxymethyl cellulose, tocopheryl acetate (vitamin E), mentha viridis (spearmint) leaf 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 #6513

SAGE[®]
PRODUCTS

Sage Products LLC

3909 Three Oaks Road | Cary, Illinois 60013

www.sageproducts.com | 800-323-2220

In Canada, imported by/Au Canada, importé par :
Cardinal Health Canada Inc. • Mississauga, ON L5T 1C2

Patents: www.sageproducts.com/patents

R5217F

PEEL HERE

NPN 02242225

TOOTHETTE[®]
Oral Care

SUCTION SWABS
with Perox-A-Mint[®] solution

For single use only

CONTENTS:

2 Suction Swabs with sodium bicarbonate
0.25 fl. oz./7mL Perox-A-Mint solution

Pour la version française, consulter le feuillet ci-inclus

Drug Facts

Active ingredient

Purpose

PEROX-A-MINT SOLUTION*:

Hydrogen peroxide 1.5%Oral Debriding Agent

Uses

- Aids in the removal of debris 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 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 Suction Swab and attach to suction line.
- Clean teeth and oral cavity for approximately 1 minute.
- To suction, place thumb over port.
- Repeat cleaning with other Suction Swab as needed.
- To clear tubing, rinse with sterile saline or

appropriate solution.

• Discard after use.

- 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 (aroma), 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.

* Manufactured for Sage Products LLC

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

Reorder #6512

SAGE[®]
PRODUCTS

Sage Products LLC

3909 Three Oaks Road | Cary, Illinois 60013

www.sageproducts.com | 800-323-2220

In Canada, imported by/Au Canada, importé par :
Cardinal Health Canada Inc. • Mississauga, ON L5T 1C2

Patents: www.sageproducts.com/patents

R5216E



SUCTION SWABS WITH PEROX-A-MINT SOLUTION
hydrogen peroxide kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-813

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-813-60	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	06/28/2002	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	2 g

Part 2		1
Part 3	1 PACKET	7 mL

Part 1 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 2 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			

Part 3 of 3

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: 059QF0K00R)	
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		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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/28/2002	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)

Establishment

Name	Address	ID/FEI	Business Operations
Sage Products LLC		054326178	manufacture(53462-813, 53462-075)

Revised: 5/2018

Sage Products LLC