

CHLORHEXIDINE GLUCONATE- chlorhexidine gluconate cloth
Sage Products LLC

Chlorhexidine Gluconate 2% Solution

2% CHLORHEXIDINE GLUCONATE CLOTH

<i>Active Ingredient</i>	<i>Purpose</i>
Chlorhexidine Gluconate 2% Solution	Antiseptic

Uses

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product
- for lumbar punctures or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not microwave
- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.

To open package

- holding top of package in one hand, lift flap on backside of package with other hand
- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to present foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination

Or

- using sterile scissors, cut off end seal of package
- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- **dry surgical sites** (such as abdomen or arm): use one cloth to cleanse each 161 cm² area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- **moist surgical sites** (such as inguinal fold): use one cloth to cleanse each 65 cm² area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any unused cloths

Other information

store product flat

store between 20-25°C (68-77°F)

avoid excessive heat above 40°C (104°F)

Inactive Ingredients

aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, nonoxynol-9, polysorbate 20, propylene glycol, USP purified water

cloth: polyester

Questions or comments?

call toll-free 800-323-2220

(Monday to Friday 8 AM - 5 PM CST)

www.sageproducts.com

DO NOT FLUSH CLOTHS

Not made with natural rubber latex

Patents:

www.sageproducts.com/patents

2 pack

Drug Facts (continued)

Or:

- using sterile scissors, cut off and seal of package
- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- dry surgical sites (such as abdomen or arm): use one cloth to cleanse each 161 cm² area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- moist surgical sites (such as inguinal fold): use one cloth to cleanse each 69 cm² area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any unused cloths

Other information

- store product flat
- store between 20–25°C (68–77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, nonoxonyl-8, polysorbate 20, propylene glycol, USP purified water, cloth: polyester

Questions or comments?

call toll-free 800-323-2220 (Monday to Friday 8:00 am – 5:00 pm CST) stryker.com



Do not flush cloths

Not made with natural rubber latex

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3919 Three Oaks Road • Cary, IL
60013 • 800 323 2220 • stryker.com
U.S. Patents: stryker.com/patents

Reorder #9705



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NDC 53462-705-20

stryker

Sage

2% Chlorhexidine Gluconate* Cloth

Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free — alcohol-free
for external use only — single use

- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application



2

Disposable cloths
7.5 in x 7.5 in (19.1 cm x 19.1 cm)
Do not microwave

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate	Antiseptic
2% solution	Antiseptic

Uses

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing / difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product
- for lumbar punctures or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

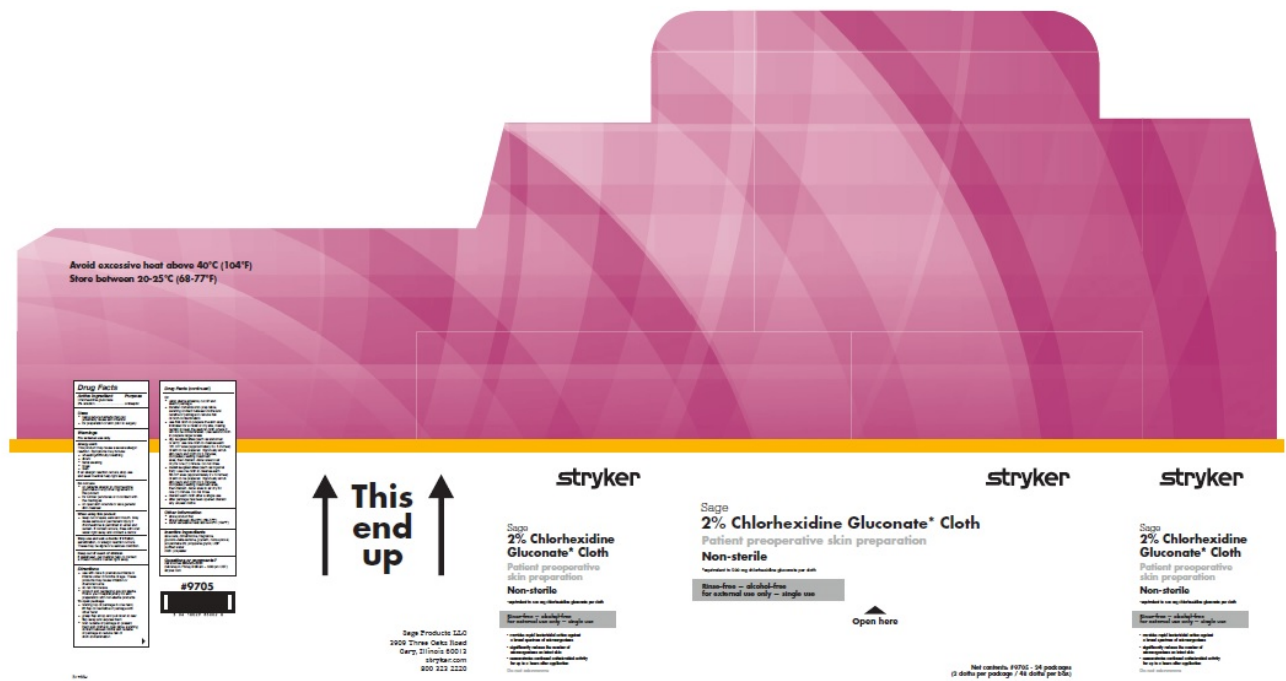
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not microwave
- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.

To open package

- holding top of package in one hand, lift flap on backside of package with other hand
- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to prevent foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination



3 x 2 packs

► Tear here ►

Drug Facts (continued)

Or

- using sterile scissors, cut off end of package
- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- dry surgical sites (such as abdomen or arm): use one cloth to cleanse each 161 cm² area (approximately 5 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- moist surgical sites (such as inguinal fold): use one cloth to cleanse each 55 cm² area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any unused cloths

Other information

- store product flat
- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients
also used, dimethylamine, fragrance, glucono-delta-lactone, glycerin, nonoxonyl-6, polyethylene glycol, USP purified water (60% polyester)

Questions or comments?
call toll-free 800-323-2200 (Monday to Friday 8:00 am - 5:00 pm CST) stryker.com

Do not
flush cloths

Does not contain natural rubber latex
Sage Products LLC
2009 Thruway Center Road • Chicago, IL 60612 • 800-323-2200 • info@stryker.com
17 A. Telerec: stryker.com/patients

Reorder #9707



NDC 53463-703-20

stryker

Sage 2% Chlorhexidine Gluconate* Cloth

Patient preoperative
skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free — alcohol-free
for external use only — single use

- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application



2

Disposable cloths
7.5 in x 7.5 in (19.1 cm x 19.1 cm)
Do not microwave

Drug Facts

Active ingredient
Chlorhexidine gluconate
2% solution Antiseptic

Uses

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

Warnings

For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
• wheezing / difficulty breathing
• shock • facial swelling
• hives • rash
If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product
 - for lumbar punctures or in contact with the meninges
 - on open skin wounds or as a general skin cleanser
- When using this product**
- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and seek a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not microwave
- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.

- To open package**
- holding top of package in one hand, lift flap on backside of package with other hand
 - grasp flap at top and pull down to tear flap away and expose foam
 - hold outside of package to prevent foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination

Avoid excessive heat above 40°C (104°F)
Store between 20-25°C (68-77°F)

Open here

Drug Facts

Active ingredient
Chlorhexidine gluconate
2% solution Antiseptic

Uses

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

Warnings

For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:
• wheezing / difficulty breathing
• shock • facial swelling
• hives • rash
If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product
- for lumbar punctures or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and seek a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- do not microwave
- product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.

To open package

- holding top of package in one hand, lift flap on backside of package with other hand
- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to prevent foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination

Reorder #9707

Does not contain natural rubber latex

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17 A. Telerec: stryker.com/patients

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Sage
2% Chlorhexidine Gluconate* Cloth
Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free — alcohol-free
for external use only — single use

- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application

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Sage
2% Chlorhexidine Gluconate* Cloth
Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free — alcohol-free
for external use only — single use

Net contents: #9707 — 16 packages
(8 cloths per package / 16 cloths per box)

stryker

Sage
2% Chlorhexidine Gluconate* Cloth
Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application

6 pack

Test here

Drug Facts (continued)

- Using sterile scissors, cut off end of package.
- Transfer contents onto prep table, avoiding contact between cloth and outside of package to reduce risk of cloth contamination.
- Use a cloth to prepare the skin area indicated for use or dry skin. Keep the remaining cloth where they will not be contaminated. Use additional cloths to prepare for larger areas.
- Dry surgical sites (such as incisions or arms), use one cloth to cleanse each 100 cm² area approximately 2 to 3 inches of skin to be prepared.
- Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- Model surgical sites (such as incisions) use one cloth to cleanse each 100 cm² area approximately 2 to 3 inches of skin to be prepared. Vigorously scrub skin back and forth for 2 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- Discard each cloth after a single use.
- After package has been opened, discard any unused cloths.

Other information

- Store product flat.
- Store between 20-25°C (68-77°F).
- Avoid excessive heat above 40°C (104°F).

Inactive ingredients

Water, dimethylamine, hydroxyglucuronide-sulfate, glycerin, monomethyl-2, propylene glycol, purified water, 0.05% preservative.

Questions or comments?

See side of box 800-323-2220.
Monday to Friday 8:00 am - 5:00 pm CST
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Sage Products LLC
3909 Three Caves Road
Cary, Illinois 60013
800 323 2220
stryker.com

U.S. Patients: stryker.com/patients

Reorder #9717



NDC 53462-705-26

stryker

Sage 2% Chlorhexidine Gluconate* Cloth

Patient preoperative
skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free - alcohol-free
for external use only - single use

- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application



6

Disposable cloths
7.5 in x 7.5 in (19.1 cm x 19.1 cm)
Do not microwave

Drug Facts

Active ingredient
Chlorhexidine gluconate
2% solution - Antiseptic

Uses
• Helps reduce bacteria that can potentially cause skin infection
• For preparation of skin prior to surgery

Warnings

For external use only

Allergy alert

This product may cause a severe allergic reaction. Symptoms may include:
• wheezing/difficulty breathing
• shock
• facial swelling
• hives
If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- on patients allergic to chlorhexidine gluconate or any other ingredient in this product.
- for further punctures or in contact with the mavericks.
- on open skin wounds or as a general skin cleanser.

When using this product

- Keep out of eyes, ears and mouth. May cause irritation or permanent injury if chlorhexidine is permitted to enter and remain in contact. Rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if irritation, redness, or allergic reaction occurs.

These may be signs of a serious condition.

Keep out of reach of children.

If needed, get medical help or contact a Poison Control Center right away.

Directions

- Use with care to prevent infection of incision under 2 months of age. These products may cause infection or chemical burns.
- Do not microwave.
- Product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products.
- To open package:**
 - Holding top of package in one hand, lift flap on backside of package with other hand.
 - Grasp flap at top and pull down to tear flap away and expose foam.
 - Hold outside of package to prevent foam and cloth to prep table, avoiding contact between cloth and outside of package to reduce risk of cloth contamination.



Do not
flush cloths

Not made with
natural rubber latex.

Avoid excessive heat above 40°C (104°F)
Store between 20-25°C (68-77°F)

Open here

Drug Facts
Directions • Use with care to prevent infection of incision under 2 months of age. These products may cause infection or chemical burns. • Do not microwave. • Product and packaging are not sterile. Follow your hospital policy for skin preparation with non-sterile products. To open package: • Holding top of package in one hand, lift flap on backside of package with other hand. • Grasp flap at top and pull down to tear flap away and expose foam. • Hold outside of package to prevent foam and cloth to prep table, avoiding contact between cloth and outside of package to reduce risk of cloth contamination.

Drug Facts (continued)
Other information • Store product flat. • Store between 20-25°C (68-77°F). • Avoid excessive heat above 40°C (104°F).
Inactive ingredients Water, dimethylamine, hydroxyglucuronide-sulfate, glycerin, monomethyl-2, propylene glycol, purified water, 0.05% preservative.
Questions or comments? See side of box 800-323-2220. Monday to Friday 8:00 am - 5:00 pm CST stryker.com

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end
up ↑

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Sage
2% Chlorhexidine Gluconate* Cloth
Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free - alcohol-free
for external use only - single use

Provides rapid bactericidal action against a broad spectrum of microorganisms

Significantly reduces the number of microorganisms on intact skin

Demonstrates continued antimicrobial activity for up to 6 hours after application

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3909 Three Caves Road
Cary, Illinois 60013
stryker.com
800 323 2220

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Sage
2% Chlorhexidine Gluconate* Cloth
Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free - alcohol-free
for external use only - single use

Provides rapid bactericidal action against a broad spectrum of microorganisms

Significantly reduces the number of microorganisms on intact skin

Demonstrates continued antimicrobial activity for up to 6 hours after application

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Sage
2% Chlorhexidine Gluconate* Cloth
Patient preoperative skin preparation

Non-sterile

*equivalent to 500 mg chlorhexidine gluconate per cloth

Rinse-free - alcohol-free
for external use only - single use

Provides rapid bactericidal action against a broad spectrum of microorganisms

Significantly reduces the number of microorganisms on intact skin

Demonstrates continued antimicrobial activity for up to 6 hours after application

Net contents: #9717 - 18 packages
(6 cloths per package / 108 cloths per box)

CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate cloth

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53462-705

Route of Administration

TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	500 mg

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53462-705-20	2 in 1 PACKAGE; Type 0: Not a Combination Product	02/01/2006	
2	NDC:53462-705-23	6 in 1 PACKAGE; Type 0: Not a Combination Product	02/01/2006	
3	NDC:53462-705-26	6 in 1 PACKAGE; Type 0: Not a Combination Product	02/01/2006	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021669	02/01/2006	

Labeler - Sage Products LLC (054326178)

Registrant - Sage Products LLC (054326178)