

NDC 17518-051-04

3M

Avagard™

(Chlorhexidine Gluconate
1% Solution and Ethyl
Alcohol 61% w/w)

Surgical and Healthcare
Personnel Hand Antiseptic
with Moisturizers

Flammable, keep away from fire or flame,
heat, sparks and sources of static discharge.

40.6 fl oz • 1200 mL

REF 9216

Drug Facts

Active ingredients

Chlorhexidine gluconate 1% w/wAntiseptic
Ethyl alcohol 61% w/wAntiseptic

Purpose

- Uses**
- **surgical hand antiseptic**; significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care
 - **healthcare personnel hand antiseptic**; hand rub to help reduce bacteria that potentially can cause disease
 - recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or flames.

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 if you are allergic to chlorhexidine gluconate or any other ingredient in this product.

When using this product:

- do not touch the eye with hands that have been treated with this preparation
- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye.
- If contact occurs, rinse with cold water right away
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

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.

Drug Facts (continued)

Directions • use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

- Surgical hand antiseptic**
- apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick.
 - dispense one pump (2 mL) into the palm of one hand
 - dip the fingertips of the opposite hand into the lotion and work it under the nails
 - spread the remaining lotion over the hand and up to just above the elbow
 - using another 2 mL of lotion, repeat with the other hand
 - dispense another 2 mL of lotion into either hand; reapply to all aspects of both hands up to the wrists
 - allow to dry before donning gloves

Healthcare personnel hand antiseptic

- apply to clean, dry hands and nails

- dispense one pump (2 mL) into the palm of one hand
- paying particular attention to the spaces between the fingers and under fingernails, apply the lotion evenly to cover both hands up to the wrists
- allow to dry without wiping

Other information store at 20-25°C (68-77°F)

Inactive ingredients Beheneth 10, behenyl alcohol, C20-40 parath-24, cetyl palmitate, diisopropyl dimer dilinoleate, dimethicone, glycerin, polyethylene glycol, squalane, water

Questions? call 1-800-228-3957

3M

Avagard™

Surgical and Healthcare
Personnel Hand Antiseptic
with Moisturizers

Flammable, keep away from fire or flame, heat,
sparks and sources of static discharge.

16 fl oz • 500 mL

NDC 17518-051-01

Peel to read Drug
Facts Panel before use

(Chlorhexidine Gluconate
1% Solution and Ethyl
Alcohol 61% w/w)

Made in U.S.A. for 3M Health Care
2510 Conway Ave., St. Paul, MN 55144
1-800-228-3957

www.3M.com/infectionprevention
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shape and colors of the bottle and
wall bracket are trademarks of 3M.

Patent: 3M.com/Patents
MAL10110039XC

REF 9200

Drug Facts

Active ingredients

Chlorhexidine gluconate 1% w/w
Ethyl alcohol 61% w/w

Purpose

Antiseptic
Antiseptic

Uses

- surgical hand antiseptic: significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care
- healthcare personnel hand antiseptic: hand rub to help reduce bacteria that potentially can cause disease
- recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or flames.

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 if you are allergic to chlorhexidine gluconate or any other ingredient in this product.

When using this product:

- do not touch the eye with hands that have been treated with this preparation

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye.
- if contact occurs, rinse with cold water right away
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

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.

Drug Facts (continued)

Directions

• use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand antiseptic

- apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick.

- dispense one pump (2 mL) into the palm of one hand
- dip the fingertips of the opposite hand into the lotion and work it under the nails
- spread the remaining lotion over the hand and up to just above the elbow
- using another 2 mL of lotion, repeat with the other hand
- dispense another 2 mL of lotion into either hand; reapply to all aspects of both hands up to the wrists
- allow to dry before donning gloves

Healthcare personnel hand antiseptic

- apply to clean, dry hands and nails
- dispense one pump (2 mL) into the palm of one hand
- paying particular attention to the spaces between the fingers and under fingernails, apply the lotion evenly to cover both hands up to the wrists
- allow to dry without wiping

Other information store at 20-25°C (68-77°F)

Inactive ingredients

benethol 10, behenyl alcohol, C20-40 pareth-24, cetyl palmitate, diisopropyl dimer dilinoleate, dimethicone, glycerin, polyethylene glycol, squalane, water

Questions? call 1-800-228-3957

**3M™ Avagard™ (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w)
Surgical and Healthcare Personnel Hand Antiseptic, NDA 21-074**

Avagard™ Product Information

PRODUCT TITLE

Avagard™

(Chlorhexidine gluconate 1% and ethyl alcohol 61%, w/w)

Surgical and Healthcare Personnel Hand Antiseptic
with moisturizers

DESCRIPTION

Avagard Antiseptic Hand Preparation with moisturizers for surgical and healthcare disinfection, provides rapid bactericidal action and persistent antimicrobial protection against a broad spectrum of organisms. Avagard antiseptic hand prep contains 1% (w/w) chlorhexidine gluconate, and 61% (w/w) ethyl alcohol in an emollient-rich lotion base.

This product is flammable, keep away from fire or flame, heat, sparks and sources of static discharge.

Avagard antiseptic hand prep does not require the use of water, or mechanical scrubbing with a surgical brush to achieve the bactericidal effect. Water should not be used in its application.

CLINICAL PHARMACOLOGY

***In vitro* Microbiology**

The following *in vitro* data are available but their clinical significance is unknown.

Time Kill Study: In an independent Time Kill Study, the speed of the microbiocidal activity of Avagard antiseptic hand prep was measured using a select battery of microorganisms. Avagard antiseptic hand prep demonstrated rapid bactericidal activity against the broad range of microorganisms tested.

Microorganism	% Microbial Kill in 15 Seconds
	Avagard™ Antiseptic hand prep
<i>Staphylococcus aureus</i> (ATCC 29213)	99.99
<i>Staphylococcus aureus</i> (ATCC 6538)	99.99
<i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	99.98
<i>Escherichia coli</i> (ATCC 11229)	99.96
<i>Escherichia coli</i> (ATCC 25922)	99.99
<i>Pseudomonas aeruginosa</i> (ATCC 15442)	99.91
<i>Pseudomonas aeruginosa</i> (ATCC 27853)	99.99
<i>Serratia marcescens</i> (ATCC 14756)	99.99
<i>Staphylococcus epidermidis</i> (ATCC 12228)	99.99*
<i>Staphylococcus epidermidis</i> (MRSE) (ATCC 51625)	99.99
<i>Micrococcus luteus</i> (ATCC 7468)	99.56
<i>Enterococcus faecalis</i> (ATCC 29212)	99.95
<i>Enterococcus faecalis</i> (VRE) (ATCC 51299)	99.48
<i>Enterococcus faecium</i> (MDR) (ATCC 51559)	99.81
<i>Candida albicans</i> (ATCC 10231)	99.98

*outlier excluded from calculation

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Surgical and Healthcare Personnel Hand Antiseptic, NDA 21-074**

Minimum Inhibitory Concentration Study¹: In an independent study, Avagard antiseptic hand prep was tested against 1058 isolates while the vehicle control and the reference product were tested against 266 isolates of the organisms listed below. Avagard antiseptic hand prep demonstrated antiseptic activity against all organisms tested.

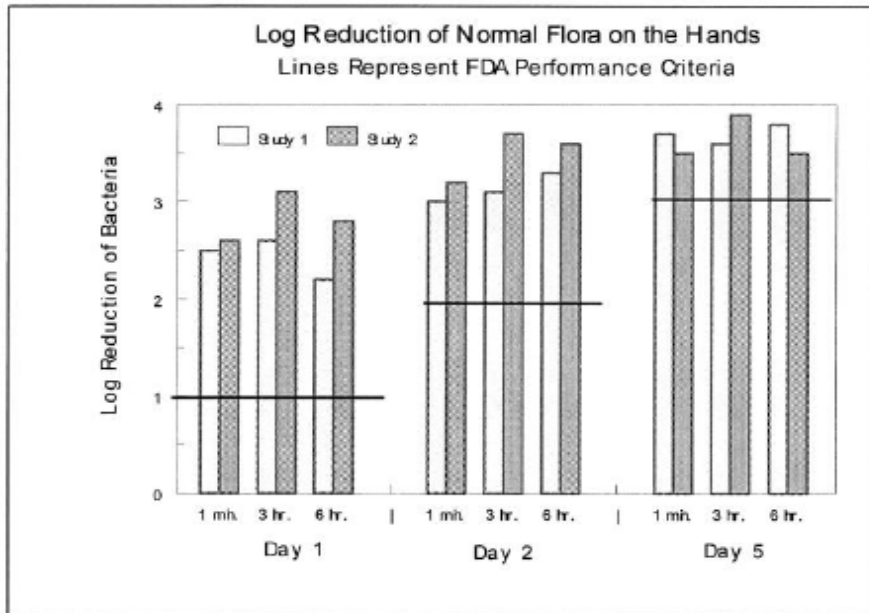
<i>Microorganism</i>	Lab Strains		Clinical Isolates	
	N	MIC Range (µg/ml)	N	MIC Range (µg/ml)
<i>Acinetobacter</i> sp.	25	2 – 16	25	2 – 32
<i>Bacteroides fragilis</i>	23	1 – 4	24	1 – 4
<i>Haemophilus influenzae</i>	25	0.5 – 4	25	0.5 – 8
<i>Enterobacter</i> sp.	25	2 – 16	25	4 – 32
<i>Escherichia coli</i>	25	2 – 8	26	2 – 8
<i>Klebsiella</i> sp.	25	0.5 – 16	25	4 – 8
<i>Pseudomonas aeruginosa</i>	25	2 – 16	29	4 – 16
<i>Proteus mirabilis</i>	25	4 – 32	25	4 – 128
<i>Serratia marcescens</i>	25	4 – 32	25	4 – 32
<i>Staphylococcus aureus</i> including MRSA	25	2 – 4	26	1 – 16
<i>Staphylococcus epidermidis</i>	24	1 – 4	28	0.5 – 4
<i>Staphylococcus hominis</i>	9	0.5 – 8	41	1 – 4
<i>Staphylococcus haemolyticus</i>	7	1 – 4	43	1 – 4
<i>Staphylococcus saprophyticus</i>	15	1 – 4	36	1 – 4
<i>Micrococcus luteus</i>	25	0.5 – 8	25	0.5 – 4
<i>Streptococcus pyogenes</i>	25	<0.25 - 2	25	0.5 – 8
<i>Enterococcus faecalis</i> including VRE	25	1 – 8	25	2 – 8
<i>Enterococcus faecium</i>	24	1 – 4	26	1 – 16
<i>Streptococcus pneumoniae</i>	25	1 – 4	27	2 – 32
<i>Candida</i> sp.	24	1 – 16	26	2 – 8
<i>Candida albicans</i>	25	4 - 16	25	4 - 16

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Clinical Studies

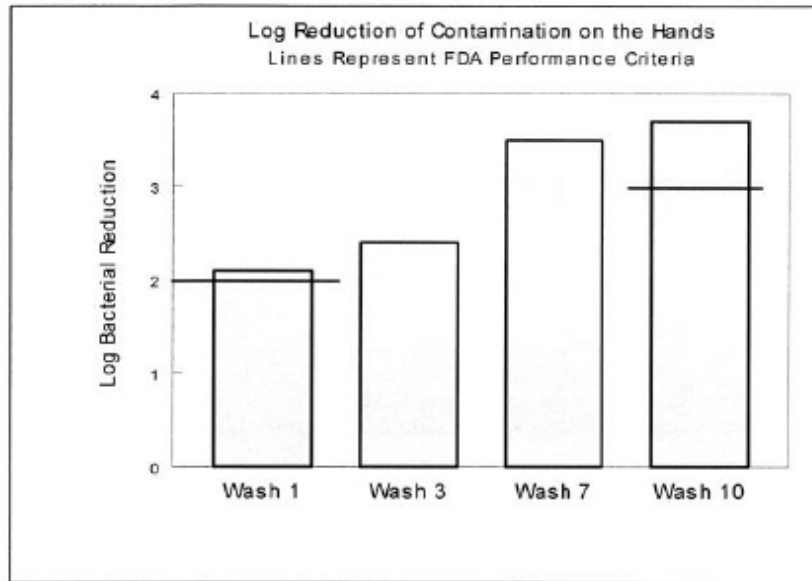
The following section details studies designed to simulate actual clinical use.

Surgical Hand Antiseptic Studies: The procedure used was the FDA specified test method for Surgical Scrub products². In two studies, the immediate bactericidal effect of Avagard antiseptic hand prep after a single application resulted in a 2.5 log reduction from a 6 log baseline (99.6%) in resident bacterial flora, with a continued 3.5 log reduction (99.96%) after the final (eleventh) scrub. Reductions on surgically gloved hands were maintained over the six-hour test period.



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Surgical and Healthcare Personnel Hand Antiseptic, NDA 21-074**

Health Care Personnel Antiseptic Study: The procedure used was the FDA specified test method for health care personnel handwash products². After one application, use of Avagard antiseptic hand prep demonstrated a 2.1 log reduction from a 7 log baseline (99.2%) of bacteria on artificially contaminated hands. After the final (tenth) application, the reduction increased to 3.7 logs (99.98%).



Safety Studies

In a Human Repeat Insult Patch Test (Jordan-King Modification of the Draize Sensitization Procedure)^{3,4} conducted in 217 subjects, Avagard antiseptic hand prep displayed no evidence suggesting a sensitization potential. In a 21-Day Evaluation of the Cumulative Irritation Potential⁵ of Avagard antiseptic hand prep and its vehicle, both articles were classified as mild materials, under occlusive and semi-occlusive conditions. The test products were allowed to dry on the skin for 15 minutes prior to patch application, which may have minimized irritation potential. However, available safety data indicates that repeated use of Avagard antiseptic hand prep was associated with little change in moisture, scaliness, erythema or tactile roughness when compared to baseline conditions.

In animal studies, Avagard antiseptic hand prep produced mild ocular irritation when instilled into the eyes of albino rabbits. Avagard antiseptic hand prep was not teratogenic when applied to the skin of rats. Avagard antiseptic hand prep has not been tested for mutagenicity or carcinogenicity.

**3M™ Avagard™ (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w)
Surgical and Healthcare Personnel Hand Antiseptic, NDA 21-074**

INDICATIONS AND USAGE

Avagard™ Antiseptic Hand Preparation is indicated for use as a surgical hand antiseptic and as a healthcare personnel hand antiseptic.

CONTRAINDICATIONS

Avagard Antiseptic Hand Preparation should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or any of its components.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.
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 IF YOU ARE ALLERGIC TO CHLORHEXIDINE GLUCONATE OR ANY OTHER INGREDIENTS IN THIS PRODUCT. KEEP OUT OF EYES, EARS AND MOUTH. IF AVAGARD ANTISEPTIC HAND PREPARATION SHOULD CONTACT THOSE AREAS, RINSE WITH COLD WATER RIGHT AWAY. Products containing chlorhexidine gluconate have been reported to cause serious and permanent eye injury if permitted to remain in the eye. Do not use routinely if you have wounds that involve more than the superficial layers of the skin. Irritation, sensitization and generalized allergic reactions have been reported with some chlorhexidine-containing products. If adverse reactions occur, discontinue use immediately, and, if severe, contact a physician. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

ADVERSE REACTIONS

There were two adverse events probably or possibly related to Avagard antiseptic hand prep use in the 85 subjects who used this product in pivotal clinical trials. One subject suffered conjunctivitis and blurred vision after he rubbed his eye with a hand that had been treated with Avagard antiseptic hand prep. The other subject developed a maculopapular rash.

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DIRECTIONS FOR USE

Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical Hand Antiseptic

1. Apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick.
2. Dispense one pump (2 ml) of lotion into the palm of the hand.
3. Dip the fingertips of the opposite hand into the lotion and work it under the nails. Spread the remaining lotion over the hand and up to just above the elbow.
4. Using another 2 ml of lotion, repeat above steps with the other hand.
5. Dispense another 2 ml of lotion into either hand and reapply to all aspects of both hands up to the wrists.
6. Allow to dry before donning gloves.

Healthcare Personnel Hand Antiseptic

1. Apply to clean, dry hands and nails.
2. Dispense one pump (2 ml) into the palm of one hand.
3. Paying particular attention to the spaces between the fingers and under the fingernails, apply the lotion evenly to cover both hands up to the wrists.
4. Allow to dry without wiping.

HOW SUPPLIED

500 ml (16 fl oz) filled plastic bottle with wall-bracket dispenser assembly (NDC #17518-051-01)

1200 ml (40.6 fl oz) filled plastic bottle with wall-bracket dispenser assembly (NDC #17518-051-04)

Store at 20-25°C (68-77°F)

INFORMATION FOR THE USER

Skin Condition Studies

Two independent 5-day handwashing studies were performed in a total of 58 subjects with normal, healthy skin, who washed with Avagard antiseptic hand prep. In these studies, use of Avagard antiseptic hand prep was associated with little change in moisture, scaliness, erythema, or tactile roughness after repeated use, when compared to baseline condition.

Made in U.S.A. for
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957

**3M™ Avagard™ (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% w/w)
Surgical and Healthcare Personnel Hand Antiseptic, NDA 21-074**

REFERENCES

1. National Committee for Clinical Laboratory Standards, "Methods for Dilution Antimicrobial Susceptibility Test for Bacteria that Grow Aerobically", Document M7-A2, Vol. 5, No. 22.
2. Tentative Final Monograph for Health Care Antiseptic Drug Products; Federal Register; Vol. 59, No. 116, Friday June 17, 1994.
3. Jordan WP, King SE. Delayed hypersensitivity in females. The development of allergic contact dermatitis in females during comparison of two predictive patch tests. *Contact Dermatitis* 3, 19-23, 1977.
4. Jordan WP: 24-, 48-, and 48/48 hour patch tests. *Contact Dermatitis* 6, 151-152, 1980.
Lanman BM, Elvers EB, and Howard CJ. The role of human patch testing in a product development program. Joint Conference on Cosmetic Sciences. The Toilets Goods Association (Currently The Cosmetic, Toiletry, and Fragrance Association), Washington, D.C., April