3M[™] Avagard[™] Foaming Instant Hand Antiseptic Product Profile

CLASSIFICATION:

Over-the-Counter (OTC) Drug Product

PRODUCT DESCRIPTION:

3M[™] Avagard[™] Foaming Instant Hand Antiseptic is a non aerosol ethyl alcohol antimicrobial product.

	Catalog Number	NDC	Product Description	Size
	9320A	17518-055-02	3M™ Avagard™ Foaming Instant Hand Antiseptic	50 mL (1.6 fl oz) bottle
	9321A	17518-055-01	3M™ Avagard™ Foaming Instant Hand Antiseptic	500 mL (16.9 fl oz) bottle
	9322A	17518-055-00	3M™ Avagard™ Foaming Instant Hand Antiseptic	1000 mL (33.8 fl oz) bottle

INTENDED USE:

3M[™]Avagard[™] Foaming Instant Hand Antiseptic is indicated for use as an instant health-care personnel hand antiseptic.

FEATURES AND BENEFITS:

- Designed to provide rapid, broad-spectrum bacterial kill.
- An emollient formulation and a waterless application method to help maintain skin condition and enhance compliance with hand hygiene protocols.
- Compatible with Chlorhexidine gluconate (CHG).
- Compatible with natural rubber latex and synthetic non-latex gloves including nitrile and vinyl (PVC).

DISPENSING SYSTEMS:

- The 50 mL and 500 mL bottle include a hand pump dispenser.
- The 1000 mL bottle fits the 9240 Universal Hands Free Wall Dispenser or the 9241Universal Manual Wall Dispenser.
- 3M[™]Avagard[™] Foaming Instant Hand Antiseptic does not utilize metered dose pumps so there is little variability in the quantity dispensed with each pump. The approximate quantity dispensed with each pump is:
 - 50 ml bottle:~ 0.40 ml

- 500 ml bottle: ~ 0.75 ml
- 1L bottle:~ 0.70 ml
- Drip trays are available for all Avagard Foaming Hand Antiseptic wall mount brackets and dispensers.
- 3M[™] Avagard[™] Foaming Instant Hand Antiseptic wall mount brackets, dispensers and drip trays conform to the Americans with Disabilities Act (ADA) Standards.

WARNINGS:

- FLAMMABLE, keep away from fire or flame.
- For external use only.
- When using this product keep out of eyes. If contact with eye occurs, rinse promptly and thoroughly with water.
- Stop use and ask a doctor if significant irritation or sensitization develops.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS FOR USE:

Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.

ACTIVE INGREDIENT:

70% v/v (62% w/w) ethyl alcohol

INACTIVE INGREDIENTS:

- Denatonium benzoate, PEG/PPG 18/18 Dimethicone, PEG-23 M, Water
- Fragrance, dye and preservative free
 - Contains no paraben
 - Contains no oils, mineral oil or petrolatum
 - pH 5 7

SHELF LIFE:

24 months

LOT CODE:

A lot represents a production quantity of hand sanitizers. At the time the product is packaged, the lot code is assigned. The lot code provides traceability for the complete history of the manufacture, control, packaging and distribution. The expiration date is provided as the abbreviated month and year. An example of the lot code and expiration date is shown below:

LOT 201101AA EXP JUN12

MICROBIOLOGY

3M[™] Avagard[™] Foaming Instant Hand Antiseptic offers fast and effective reduction against a broad spectrum of microorganisms. Table below lists percent kill of each organism at each time point tested.

Organism	15 sec.	30 sec.	60 sec.
Acinetobacter baumannii, ATCC 19606	>99.9999	>99.9999	>99.9999
Bacteroides fragilis, ATCC 25285	>99.999	>99.999	>99.999
Candida albicans, ATCC 10231	>99.9999	>99.9999	>99.9999
Candida glabrata, ATCC 26512	>99.9999	>99.9999	>99.9999
Enterobacter aerogenes, ATCC 13048	>99.9999	>99.9999	>99.9999
Enterococcus faecalis, ATCC 29212	>99.9999	>99.9999	>99.9999
Enterococcus faecalis (VRE), ATCC 51299	>99.9999	>99.9999	>99.9999
Enterococcus faecium, ATCC 19434	>99.9999	>99.9999	>99.9999
Escherichia coli, ATCC 11229	>99.9999	>99.9999	>99.9999
Escherichia coli, ATCC 25922	>99.9999	>99.9999	>99.9999
Haemophilus influenzae, ATCC 19418	>99.9999	>99.9999	>99.9999
Klebsiella pneumoniae, ATCC 4352	>99.9999	>99.9999	>99.9999
Micrococcus luteus, ATCC 7468	>99.9999	>99.9999	>99.9999
Proteus mirabilis, ATCC 7002	>99.9999	>99.9999	>99.9999
Pseudomonas aeruginosa, ATCC 15442	>99.9999	>99.9999	>99.9999
Pseudomonas aeruginosa, ATCC 27853	>99.9999	>99.9999	>99.9999
Serratia marcescens, ATCC 14756	>99.9999	>99.9999	>99.9999
Staphylococcus aureus, ATCC 6538	>99.9999	>99.9999	>99.9999
Staphylococcus aureus, ATCC 29213	>99.9999	>99.9999	>99.9999
Staphylococcus aureus (MRSA), ATCC 33592	>99.9999	>99.9999	>99.9999
Staphylococcus epidermidis, ATCC 12228	>99.9999	>99.9999	>99.9999
Staphylococcus epidermidis (MRSE), ATCC 51625	>99.9999	>99.9999	>99.9999
Staphylococcus haemolyticus, ATCC 29970	>99.9999	>99.9999	>99.9999
Staphylococcus hominis, ATCC 27844	>99.999	>99.999	>99.999
Staphylococcus saprophyticus, ATCC 15305	>99.9999	>99.9999	>99.9999
Streptococcus pneumoniae, ATCC 33400	>99.999	>99.999	>99.999
Streptococcus pyogenes, ATCC 19615	>99.999	>99.999	>99.999

ENVIRONMENT:



Avagard[™] Foaming Instant Hand Antiseptic is packaged in high-density polyethylene bottles.

Unless otherwise specified empty Avagard containers may be recycled.

RECOMMENDED DISPOSAL PROCESS:

- Pump cap should be removed from the bottle and disposed of in general refuse.
- Empty bottles should be rinsed thoroughly with water and drained and placed with recyclable plastic waste.

MSDS:

Available on-line at: http://solutions.3m.com/wps/portal/3M/en_US/infection-preventionsolutions/home/infection-prevention/hand-hygiene/

FOR ANSWERS TO QUESTIONS ABOUT 3M[™] AVAGARD[™] FOAMING INSTANT HAND ANTISEPTIC CALL 1 – 800-228-3957 (MONDAY TO FRIDAY 7AM – 6PM CST)