

3M™ Avagard™ D Instant Hand Antiseptic for Healthcare Personnel Product Profile

CLASSIFICATION:

Over-the-Counter (OTC) Drug Product

REGULATORY REFERENCES:


Avagard™ D Instant Hand Antiseptic meets the specifications for an instant health-care personnel hand antiseptic established by the US Food and Drug Administration’s (FDA) Tentative Final Monograph for Health-Care Antiseptic Drug Products (TFM) ¹.

COUNTRY OF ORIGIN:

Made in the U.S.A. for 3M Health Care

PRODUCT DESCRIPTION:

Ethyl alcohol hand antiseptic in an emollient-rich lotion base.

	Catalog Number	NDC Number	Product Description	Size
	9221	17518-050-01	Personal size bottle with flip top cap	88mL (3 oz.) 48 / case
	9222	17518-050-02	Bottle with hand pump dispenser	500mL (16.9 oz) 12 / case
	9230	17518-050-00	Wall mount bottle fits the 9240 Universal Hands Free Wall Dispenser or the 9241 Universal Manual Wall Dispenser.	1000 mL (33.8 fl. oz.) 6 / case

INTENDED USE:

3M™ Avagard™ D 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.
- Emollient rich formulation to help maintain skin condition and enhance hand hygiene compliance.
- Compatible with Chlorhexidine gluconate containing hand hygiene products (CHG).
- Compatible with natural rubber latex and synthetic non-latex gloves including nitrile and vinyl (PVC).

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:

61% w/w ethyl alcohol

INACTIVE INGREDIENTS:

- beheneth 10, behenyl alcohol, C20-40 pareth-24, cetyl palmitate, diisopropyl dimer dilinoleate, dimethicone, glycerin, polyethylene glycol, squalane, water
- Fragrance, dye and preservative free.
 - Contains no paraben.
 - Contains no oils, mineral oil or petrolatum.

MICROBIOLOGY

Avagard™ D provides fast and effective reduction against a broad spectrum of microorganisms killing greater than 99.999% kill of harmful bacteria in 15 seconds (*in vitro*)².

SKIN HEALTH

Avagard™ D contains moisturizers which have been shown improve skin condition, healing the source of the irritation; prevent dry cracked skin, erythema and tactile roughness which are factors in skin damage. Similarly Avagard Instant Hand Antiseptics are preservative free which greatly decreases the possibility of allergic contact dermatitis².

GLOVE COMPATIBILITY

Avagard D instant hand antiseptic does not significantly decrease the tensile strength or the elongation of exam gloves⁶.

DISPENSED VOLUME:

Avagard™ D does not utilize metered dose pumps so there is a little variability in the quantity dispensed with each pump. The approximate quantity dispensed with each pump is:

- 88 ml bottle: Variable
- 500 ml bottle: ~ 1.0 ml
- 1L bottle:~ 1.0 ml

WARNINGS:

- 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.

SHELF LIFE:

- 3-year shelf life (9221 and 9222)
- 2-year shelf life (9230)

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

ENVIRONMENT:

- **Environmental surfaces:** Alcohol containing products have the potential to cause varying degrees of cosmetic damage depending on the material the alcohol contacts. Care should be taken in selection and placement of dispensers. Dispensers mounted over or set on materials susceptible to damage from contact with ethanol, wood finishes, carpet and solid surface countertops, should be fitted with drip trays or a suitable barrier to prevent damage. The most effective way to prevent cosmetic damage is to thoroughly clean under and around dispensers regularly.
- **Recommended Disposal Process:** Empty Avagard™ D containers should be disposed of according to all applicable State and Federal environmental regulations. If the recycling of empty containers is permitted the following steps are recommended.
 1. Pump cap should be removed from the bottle and disposed of in general refuse.
 2. Empty bottles should be rinsed thoroughly with water and drained and placed with recyclable plastic waste
- **Recyclable Material**



3M™ Avagard™ D is packaged in high-density polyethylene bottles.

Unless otherwise specified empty Avagard containers may be recycled.

Point of Care*:**Brackets and Dispensers**

Note: Avagard™ D Instant Hand Antiseptic wall mount brackets, dispensers and drip trays conform to the Americans with Disabilities Act (ADA) Standards.

Catalog Number	Description	Corresponding Container	Dimensions
9226	3M™ Avagard™ D Wall Bracket (purple)	Use with 9222, 9222C – 500 mL Pump bottle and 9321A	3.44" w x 8.44" h x 3.8"
9236	3M™ Avagard™ D Wall Bracket (white)		
9240	3M™ Avagard™ Hands Free Wall Dispenser	Use with 9230 and 9322A	7.3" w x 12.5" h x 4.0" d.
9241	3M™ Avagard™ Manual-Push Dispenser		7.2" w x 11.9" h x 4.0" d
9244	3M™ Avagard™ Floor Stand	Use with 9226,9236,9240 and 9341	18"W x 54 3/4" h X 18" d.

* (Available through your 3M Infection Prevention representative)

Accessories:

- Drip trays are available for all Avagard™ D Instant Hand Antiseptic wall mount brackets and dispensers.

MSDS:

Available on-line at: http://solutions.3m.com/wps/portal/3M/en_US/infection-prevention-solutions/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)

1. Federal Register Part III, Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule. Vol. 59, No 116, (Friday June 17, 1994). Code of Federal Regulations; Title 21 CFR Parts 333 and 369.
2. Technical Information Bulletin 3M™ Avagard™ D Instant Hand Antiseptic for Healthcare Personnel Use Copyright © 3M (IPC) 2000. All rights reserved. 70-2009-3003-3 WG