

TECHNICAL REPORT

<u>DESCRIPTION</u> – PROFESSIONAL AMPHYL? II DISINFECTANT DEODORANT SPRAY disinfects and deodorizes hard nonporous, environmental surfaces that may be contaminated with pathogenic bacteria, fungi and viruses.

ACTIVE INGREDIENT:	Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium saccharinate	6
INERT INGREDIENTS: *		6

^{*} Includes sodium nitrate.

EPA REG. NO. 777-72-675 EPA EST NO. 777-NJ-2 11525-IL-01



DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SAFETY REMINDER: Before employees use this or any other product, make sure they read and understand the product label, Material Safety Data Sheet and facility cleaning / disinfection protocol.

FOR DISINFECTING:

Professional AMPHYL® II Disinfectant Deodorant Spray kills microorganisms on environmental surfaces.

TO DISINFECT: Hold can upright 6" to 8" from surface. Spray precleaned surfaces 2 to 3 seconds until covered with mist. Allow to stand for 10 minutes to air dry.

TO SANITIZE: Let stand for 30 seconds.

TO DEODORIZE: Hold can upright. Spray on surfaces as needed.

ELIMINATES ODORS: Professional AMPHYL® II Disinfectant Deodorant Spray deodorizes by killing the microorganisms that cause odors. To eliminate odors retained in fabrics, spray on draperies, curtains and upholstered furniture. Spray on surfaces to eliminate damp musty odors in areas where air does not circulate.

SUGGESTED AREAS OF APPLICATION FOR PROFESSIONAL AMPHYL? II DISINFECTANT DEODORANT SPRAY: Recommended for use in hospitals, nursing homes, clinics, dental offices, physician offices, ambulances, kennels, veterinary offices, day care centers, health clubs, toilet areas, patient rooms, operatories, waiting rooms, and laboratories.

MICROBIOLOGY DATA

Mechanism of Action for Disinfectant Antimicrobial Agents

Generally, disinfectants destroy bacteria by attacking the cytoplasmic membranes or the cellular cytoplasm itself. The action of an antimicrobial agent on a bacterial cell involves first adsorption to the cell surfaces, then penetration of the outer membrane b reach these target sites.

All bacteria contain a cell wall that is unique to this group of organisms. The cell wall gives the cell its shape and rigidity. It is composed of peptidoglycan which is a polymer consisting of a disaccharide repeating unit of two different Nacetylated amino sugars, one of which is attached to a short peptide chain. Individual glycan strands are cross-linked through peptide bonds between the peptide chains. Gramnegative bacteria contain an outer cytoplasmic membrane consisting of lipopolysaccharide (LPS) molecules that surround the cell wall. The outer membrane is unique to Gram-negative bacteria. In addition, these organisms have an inner cytoplasmic membrane on the inside of the cell wall, which is in contact with the cytoplasm. It consists of phospholipids and proteins. The cytoplasmic membrane serves as the selective permeability barrier between the cytoplasm and the cell environment. It is the site at which many of the important cellular functions occur and the target site for many antimicrobial agents. Gram-positive bacteria do not have an outer membrane, only the inner membrane.

Alcohols, such as ethanol and isopropanol, denature proteins found in bacteria. They disrupt cellular membranes. Ethanol produces a rapid release of intracellular constituents. Disorganization of the membrane probably results from penetration of the solvent into the hydrocarbon interior of the cytoplasmic membrane.

Bacteria cell walls are negatively charged thereby "attracting" positively charged cations such as quaternary ammonium compounds (QAC). QACs adsorb onto the cell surface and diffuse through the cell wall. Once inside the cell, QACs bind to the cytoplasmic membrane causing disruption. This results in the release of potassium (K+) ions and other cytoplasmic constituents. Precipitation of the cellular materials results in the death of the organism.

GERMICIDAL ACTIVITY

Test Method: Germicidal spray products method as described by Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC).

The AOAC Germicidal Spray Test determines disinfectant activity for germicidal sprays. *Staphylococcus aureus* and *Salmonella choleraesuis* are tested to support broadspectrum disinfectant activity claims. Germicides that are intended for use in hospitals or other health care facilities must also be tested against *Pseudomonas aeruginosa*. Additional organisms that may be clinically significant can also be tested as an option.

One inch by one inch glass cover slides are inoculated with 0.01 ml of a bacterial broth culture. The contaminated carriers are then dried for approximately 30 minutes at 37°C. This now represents a nonporous, hard, inanimate surface contaminated with a dried film of bacteria. The contaminated carriers are then sprayed with the disinfectant and held for a 10-minute contact time at 20°C. After treatment, the carriers are placed in 10 ml subculture broth media containing appropriate neutralizers. The subculture tubes are incubated 48-54 hours at 37°C. The tubes are examined for growth as determined by turbidity of the media. An effective disinfectant for hospital use kills all the bacteria on 59 or 60 out of 60 carriers tested against S. aureus, S. choleraesuis and P. aeruginosa. For additional organisms, all the bacteria on 10 out of 10 carriers tested must be killed.

Test Conditions: Professional AMPHYL® II Disinfectant Deodorant Spray. Test culture with 5% blood serum. Contact time 10 minutes at room temperature.

Test Results:

	Number of Ca	rriers
Test Organism	Exposed	Showing Growth
Staphylococcus aureus ATCC 6538	180	0
Salmonella choleraesuis ATCC 10708	180	0
Pseudomonas aeruginosa ATCC 15442	180	0
Campylobacter jejuni ATCC 29428	20	0
Enterobacter aerogenes ATCC 13048	20	0
Enterococcus faecalis ATCC 828	20	0
Escherichia coli ATCC 1129	20	0
Klebsiella pneumoniae ATCC 9997	20	0
Listeria monocytogenes ATCC 7644	20	0
Proteus vulgaris ATCC 9920	20	0
Serratia marcescens ATCC 8195	20	0
Shigella dysenteriae ATCC 11835	20	0
Staphylococcus aureus ATCC 33592	20	0
(methicillin/gentamicin resistant)		
Streptococcus pyogenes ATCC 12384	20	0
Corynebacterium diphtheriae	10	0
Neisseria elongata	10	0
Mycobacterium tuberculosis var bovis*	10	0

^{*}See following page for methodology

TUBERCULOCIDAL ACTIVITY

Test Method: Test method as described by Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC).

The AOAC Tuberculocidal Test uses Mycobacterium bovis (BCG) as the test organism. The organism is grown 21-25 days at 37°C. in modified Proskauer-Beck Medium. One milliliter (1 ml) of a 0.1% Tween 80 solution is added to the culture which is then macerated in a sterile glass tissue grinder to produce a smooth cell suspension. The culture is then adjusted with additional fresh medium to give 20% T at 650 mm on a Spectronic-20. Porcelain penicylinder carriers are soaked in this adjusted culture for 15 minutes. Each contaminated carrier is placed into 10 ml of the germicidal solution for 10 minutes at 20°C. After the 10 minutes contact time, the carriers are removed from the germicide and placed into 10 ml of a neutralizer for 10 minutes. The carriers are then removed from the neutralizer and placed into 20 ml Modified Proskauer-Beck Medium. Two milliliters (2 ml) of the neutralizer broth are then added to 18 ml Middlebrook Broth and 18 ml Kirchner Medium. All the tubes are incubated 60 days at 37°C. If no growth is observed at the end of 60 days, the tubes are incubated an additional 30 days. An effective tuberculocidal agent kills all the organisms on all the carriers tested.

Test Conditions: Professional AMPHYL® II Disinfectant Deodorant Spray. Test culture with 5% blood serum. Contact time as specified.

Test Results: Mycobacterium tuberculosis var bovis (BCG)

	Number Tubes +			
Number of Rings Tested	Proskauer-Beck Middlebrook Kirchner			
10	0	0	0	

VIRUCIDAL ACTIVITY

Test Method: Virucidal activity -test method as described in the EPA Guidelines for Registering Pesticides, Federal Register 40 (123) 26836, 6/25/75.

In order to claim and register activity as a virucidal disinfectant, the appropriate test procedures must be performed. Since there are no "prototype" viruses, every claim of activity against a specific type of virus must be substantiated with testing against that virus.

All tests for hard surface disinfectant virucidal efficacy must be performed on a virus that has been dried onto the surface of a carrier (e.g. petri plate). Since no specific method is currently recommended for testing this efficacy, data that is submitted must meet certain criteria:

- 1. No virus-specific cytopathic effect can be detected in the lowest non-cytotoxic dilution or any of the virus/disinfectant dilutions tested.
- 2. The reduction in virus titer for each of the two batches of the test substance must be =3 logs of inactivation.
- 3. The virus titer recovered from the carrier must exceed 104

As a result, any test of virucidal efficacy must contain three basic components. The first component is the virus control, which quantitates the amount of virus present before treatment with the disinfectant. This is done by re-suspending dried virus with a standard solution, e.g. tissue culture medium, and assaying in a susceptible host. The second component is the virus/disinfectant treatment, which looks at how much virus is surviving after treatment with the disinfectant. This is done by treating the dried virus with the disinfectant, waiting the allotted contact time, and assaying for the presence of residual virus in the susceptible host. The final component is the toxicity control, which looks at the deleterious effect of the disinfectant on the host without any virus present. This is done by drying a solution that is identical in composition to the virus suspension, but lacks the virus. This dried suspension is then treated in a manner identical to the virus/disinfectant, and then assayed in the host to assess the extent of the deleterious effects due specifically to the disinfectant.

Test Conditions: Professional AMPHYL® II Disinfectant Deodorant Spray diluted with 5% fetal calf serum soil load. Contact time as specified.

Test Results:

TEST VIRUS	HOST	UNTREATED VIRUS TITER (CONTROL)	TREATED VIRUS TITER	%INACT BATCH #1	TIVATION BATCH #2
HIV-1 (AIDS Virus)*	MT2	10-4.67	<10-05	>99.99	>99.99
Adenovirus Type 2	Hep-2	10-65	<10-15	>99.99	>99.99
Cytomegalovirus	SF	10-667	<10-15	>99.9	>99.9
Echovirus Type 12	LLC-MK2	10-4.83	<10-05	>99.99	>99.99
Hepatitis A Virus	FRhK-4	10-60	<10-15	>99.9	>99.9
Herpes Simplex Virus Type 1	VERO	>10-65	<10-15	>99.99	>99.99
Herpes Simplex Virus Type 2	VERO	10-55	<10-25	>99.99	>99.99
Influenza A₂ (Japan 305/57)	Chick embryo	10-66	<10-1	>99.99	>99.99
Influenza Type B	MA-104	10-55	<10-15	>99.99	>99.99
Poliovirus Type 1	VERO	10-5.67	<10-25	>99.9	>99.9
Respiratory Syncytial Virus	Hep-2	10-66	<10-25	>99.9	>99.9
Rhinovirus Type 39	MRC-5	10-55	<10-25	>99.9	>99.9
Rotavirus	MA-104	10-55	<10-25	>99.9	>99.9
Vaccinia	Vero	10-66	<10-15	>99.99	>99.99

^{*}Tested in the presence of 50% whole human blood.

All viruses treated with Professional AMPHYL® II Disinfectant Deodorant Spray were completely inactivated. Complete inactivation indicated at least three logs of virus were inactivated with no residual virus detected within limits allowed by the toxicity of the germicide.

FUNGICIDAL ACTIVITY

Test Method: Germicidal spray products method as described by the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC).

The Germicidal Spray Test determines disinfectant activity for germicidal sprays. *Staphylococcus aureus* and *Salmonella choleraesuis* are tested to support broad spectrum disinfectant activity claims. Germicides that are intended for use in hospitals or other health care facilities must also be tested against *Pseudomonas aeruginosa*. This method can also be used to determine fungicidal activity against pathogenic fungi.

One inch by one inch glass cover slides are inoculated with 0.01 ml of a yeast broth culture or mold spore suspension. The contaminated carriers are then dried for approximately 30 minutes at 37°C. This now represents a nonporous, hard inanimate surface contaminated with a dried film of pathogenic fungi. The contaminated carriers are then sprayed with the disinfectant and held for a 10-minute contact time at 20°C. After treatment, the carriers are placed in 10 ml subculture broth media containing appropriate neutralizers. The subculture tubes are incubated under appropriate conditions for the test organisms. The tubes are examined for growth as determined by turbidity of the media. An effective disinfectant kills all the organisms on 10 out of 10 carriers tested.

Test Conditions: Professional AMPHYL® II Disinfectant Deodorant Spray. Test culture with 5% blood serum. Contact time as specified.

Test Results:

	Number of Carriers		
Test Organism	Exposed	Showing	
		Growth	
Aspergillus niger ATCC 6275	20	0	
Candida Albicans ATCC 10231	20	0	
Trichophyton mentagrophytes ATCC 9533	20	0	

FUNGISTATIC ACTIVITY

Procedure: Hard Surface Mildew Fungistatic Test – as described in the Federal Register, "Environmental Protection Agency Guidelines for Registering Pesticides", June 25, 1975, Vol. 40 No. 123, P. 26851.

Test Conditions: Professional AMPHYL® II Disinfectant Deodorant Spray. Test culture with 5% blood serum. Contact time as specified.

Test Results:

Untreated Control Tiles		Aspergillus niger ATCC 6275 Tiles treated with Professional AMPHYL® II Disinfectant Deodorant Spray			
Tile	7 Days	Tile	7 Days	30 Days	
1	++++	1	0	0	
2	++++	2	0	0	
3	++++	3	0	0	
4	++++	4	0	0	
5	++++	5	0	0	
6	++++	6	0	0	
7	++++	7	0	0	
8	++++	8	0	0	
9	++++	9	0	0	
10	++++	10	0	0	

0 - No Growth

++++ - Excessive Growth

PHYSICAL DATA

	PHYSICAL PROPERTY /
CHARACTERISTIC	TEST RESULT
Appearance	Clear liquid
Odor	Light scent
Propellant Type	Carbon dioxide
pH, with Propellant @ 25°C	10.0
pH, without Propellant @ 25°C	8.0
Density/Specific Gravity @ 25°C	0.0835
Pressure, psig @ 25°C	100
Flash Point – loading concentrate	70°F (Tag Closed Cup)
Phosphates, % as P	None
Shelf Life	+2 years
Stability (Freeze/Thaw)	Pass 3 Cycles

SANITIZATION ACTIVITY

Test Method: Test method based on the official ASTM method E1153-87: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces".

The sanitization test method supports claims of 99.9% bacterial reduction in 30 seconds. *Staphylococcus aureus* and *Klebsiella pneumoniae* are the two representative organisms. Additional organisms may be tested. 99.9% reduction in 30 seconds guarantees a quick and effective sanitization on hard nonporous surfaces

15 one inch by one inch glass cover slides per organism plus positive and negative controls are inoculated with 0.01 ml of a bacterial broth culture. The contaminated carriers are then dried for approximately 40 minutes at 37°C. This now represents a nonporous, hard, inanimate surface contaminated with a dried film of bacteria. The contaminated carriers are then sprayed with the disinfectant and held for a 30 second contact time at 20°C. After treatment, the carriers are placed in 10 ml subculture broth media containing appropriate neutralizers. Each neutralizer subculture tube containing a test or control replicate slide is vortexed for 10 to 15 seconds. Serial dilutions and plating are then performed to enumerate exact number of surviving bacteria and compare that number to negative control.

An effective sanitizer will meet the following criteria:

- ?? Each batch of the test substance must demonstrate a mean bacterial reduction of at least 99.9% over the parallel non-active control count.
- ?? The neutralizer must be shown to be effective, non-toxic and support the growth of a low number of organisms.
- ?? Organisms must be recoverable from the test surface at a concentration of at least 10⁴ CFU per slide for non-active control replicates and the dried organism recovery control replicates.

Test Conditions: Professional AMPHYL® II Disinfectant Deodorant Spray. Test culture with 5% blood serum. Contact time 30 seconds at room temperature.

Test Results:

Test Organism	% Reduction
Klebsiella pneumoniae	>99.9%
Staphylococcus aureus	>99.9%

HMIS HAZARD RATING

NFPA HAZARD RATING

Health	1	Slight	Health	1	Slight
Flammability	3	Serious	Fire	Level 1	Aerosol*
Reactivity	0	Minimal	Reactivity	0	Negligible

HMIS – Hazardous Material Identification System

NFPA – National Fire Protection Association

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

KEEP OUT OF REACH OF CHILDREN

WARNING: Causes eye irritation. Do not spray in eyes or on skin or clothing.

FIRST AID: In case of eye contact, IMMEDIATELY flush eyes thoroughly with water, remove any contact lenses, and continue to flush eyes with plenty of water for at least 15 minutes. Consult a physician if irritation persists.

PHYSICAL HAZARDS:

FLAMMABLE: Contents under pressure. Do not use near heat, sparks or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not use on polished wood, rayon fabrics, leather or acrylic plastics.

STORAGE / DISPOSAL: Store in original container in areas inaccessible to small children. Do not reuse empty container. Replace cap and discard in trash. Do not incinerate or puncture.

^{*} This is a Level 1 aerosol. This rating applies to the product concentrate and not the finished, sealed aerosol product.

MORE INFORMATION:

Satisfaction Guaranteed: Careful laboratory control assures materials of uniform quality at all times. All Reckitt Benckiser Professional products are guaranteed to give complete satisfaction, when used as directed, or they may be returned for credit.

Professional AMPHYL® II Disinfectant Deodorant Spray is part of a system of infection control products provided by Reckitt Benckiser Professional.

QUESTIONS? COMMENTS? CALL 1-800-677-9218

VISIT US AT: www.reckittprofessional.com

Aerosol can is made from an average of 25% recycled steel (10% post consumer). Contains no CFCs or other ozone depleting substances.

DISTRIBUTED BY:

RECKITT BENCKISER INC. 1655 VALLEY ROAD WAYNE, NEW JERSEY 07474-0977

PACKAGING DESCRIPTION Professional AMPHYL® II Disinfectant Deodorant Sprays			
ORDER NO.	SIZE	CASE CUBE	
36241-08300	13 oz. Aerosol Can with Standard Sprayer, 12 per case	0.46	



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N-1669-0801