Sealed Air
Diversey Care

Health Canada Regulations

Disinfectants /Hand Hygiene Products

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Objectives

Review the Health Canada documents on registering disinfectants

Review the Health Canada documents on registering hand hygiene products

Try to keep you awake for 45 minutes!

Acronyms

AOAC

- 1884 Association of Official Agricultural Chemists
- Association of Official Analytical Chemists
- The Association of Analytical Communities International

ATCC

- American Type Culture Collection

ASTM

- American Society of Testing Materials
- American Society of Testing and Materials
- ASTM International

Health Canada Santé Canada

Guidance document - Disinfectant drugs

January 2014

34 Pages of fun, excitement, suspense!

Definition

Drug: used for

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals;

(b) restoring, correcting or modifying organic functions in human beings or animals; or

(c) disinfection in premises where food is manufactured, prepared or kept.

Definitions

Antimicrobial Agent: *a drug that is capable of destroying pathogenic micro-organisms and that is labelled as being for use in the disinfection of environmental surfaces or medical devices, as defined by the Medical Devices Regulations, that (a) are not invasive devices as defined in those Regulations; and*

(b) that are intended to come into contact with intact skin only.

Definitions

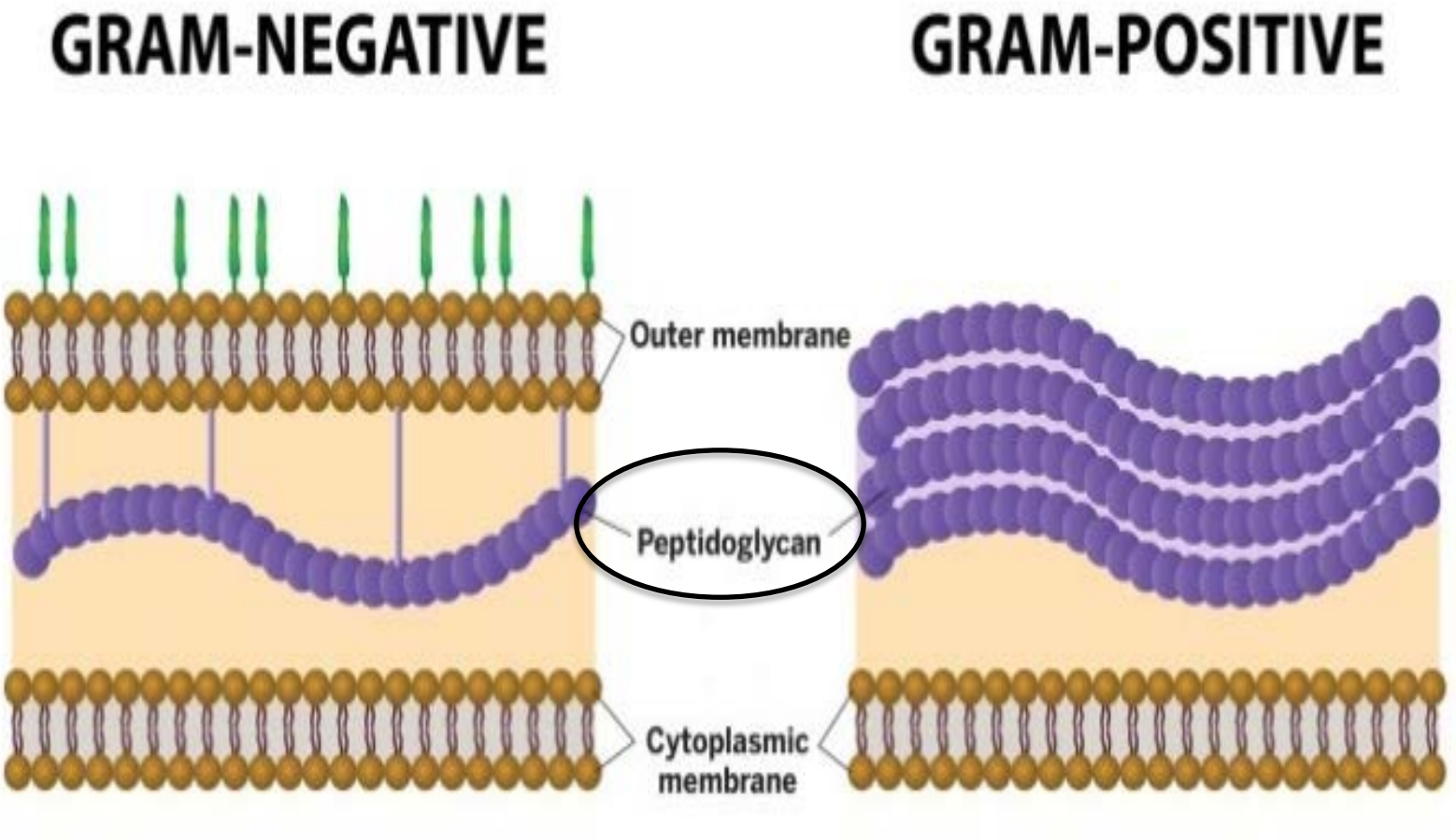
***Cide** – Destroys

- Bacteri-
- Fungi-
- Viru-

***stat** – Inhibits

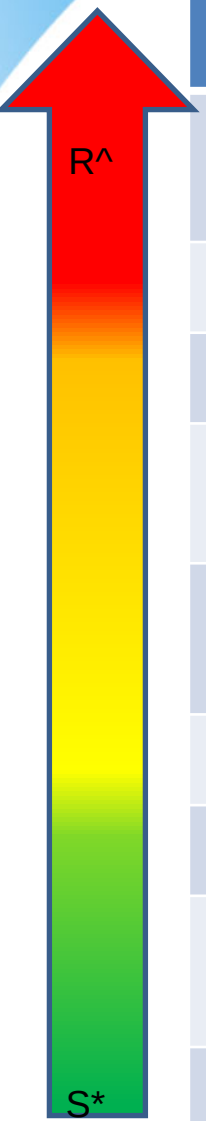
- Bacteri-
- Fungi-
- Viru-

Cell Wall



cen.acs.org

Effect of Disinfectants on Microorganisms



^Resistant
* Sensitive

Organism	Type	Examples
Bacterial Spores	Spore	*Bacillus anthracis, Clostridium difficile*
Mycobacteria	Bacteria	*M. tuberculosis*
Small non-enveloped virus	Virus	Poliovirus, Norovirus, Rhinovirus
Fungal spores	Fungus	Aspergillus, Penicillium, Trichophyton
Gram negative bacteria	Bacteria	*E. coli*, Klebsiella including CRE, Pseudomonas, Acinetobacter
Fungi (Vegetative)	Fungus	Candida
Large Virus (non-enveloped)	Virus	Adenovirus, Rotavirus
Gram positive bacteria	Bacteria	Staphylococcus including MRSA Enterococcus including VRE
Virus (enveloped)	Virus	HIV, HBV, HCV, Influenza

Adapted from Rutala et al. ICHE 2014;35(7):862

Definitions

General disinfectant: …capable of destroying both Gram-positive bacteria and Gram-negative bacteria present on environmental surfaces and inanimate objects. Also referred to as a *broad-spectrum disinfectant*, however applicants are encouraged to use the preferred term *general disinfectant* on their labelling

Definitions

Hospital disinfectant: …capable of destroying both Gram-positive bacteria and Gram-negative bacteria present on non-critical medical devices, environmental surfaces and inanimate objects, and that is represented for use in hospitals, medical clinics, dental offices or any other healthcare-related facility

Definitions

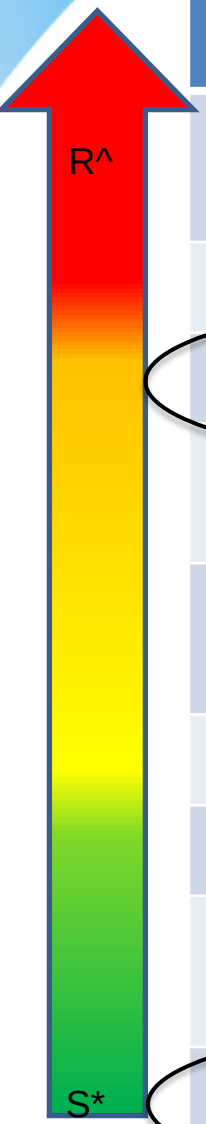
One-step cleaner/disinfectant: …that has been tested and found to be effective in the presence of light to moderate amounts of soil (e.g., a 5% organic soil load), and therefore may be used without a pre-cleaning step for light to moderate amounts of soil in the labelled directions for use.

Definitions

Broad-Spectrum Virucide – kill one representative hard to kill non-enveloped virus, and which is expected to inactivate other enveloped and non-enveloped viruses

Virucide – Kills viruses. “Disinfectants with efficacy at a minimum against any specific virus can be registered as a virucide”

Effect of Disinfectants on Microorganisms



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Adapted from Rutala et al. ICHE 2014;35(7):862

Definitions

Food Contact Surface Sanitizer: reduces bacteria on surfaces…which may come into direct contact with food or beverages (e.g., eating and drinking utensils, cutting boards, countertops, food processing equipment) by…a minimum 3 log10 reduction…

Disinfectants

Regulated by their purpose, not chemical composition

Factors:

- Intended use (expressed or implied claims on label)
- Type of surface or object to which it is intended to be applied

Natural Health Products Directorate

Regulatory body within Health Canada that assesses applications for products that are represented for use as:

- disinfectants for use on non-critical medical devices and hard non-porous environmental surfaces and inanimate objects in domestic, industrial/institutional, hospital, food processing and/or barn premises

X
- high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices

X
- contact lens disinfectants

Natural Health Products Directorate

Disinfectant drugs require a pre-market assessment and assignment of a drug identification number (DIN) prior to being sold in Canada

For a DIN to be issued for a disinfectant regulated as a drug, the product must be established by the NHPD to be safe and effective for its intended use

Acceptable Test Methods

AOAC International

ASTM International

Australian Therapeutic Goods Administration (TGA)

European Committee for Standardization (CEN)

- Comité Européen de Normalisation

International Organization for Standardization (ISO)

- *Based on Greek word ISOS - equal*

Organisation for Economic Co-Operation and Development (OECD)

United States Environmental Protection Agency (U.S. EPA)

United States Food and Drug Administration (U.S. FDA)

United States
Environmental Protection
Agency

Office of Chemical Safety and
Pollution Prevention
(7510P)

EPA 712-C-07-005
September 4, 2012

EPA

Product Performance Test Guidelines

OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents

Designation: E2562 – 12

Standard Test Method for Quantification of *Pseudomonas aeruginosa* Biofilm Grown with High Shear and Continuous Flow using CDC Biofilm Reactor[1]

Testing Methods

Uses glass vials

Cannot be done for viruses

Designation: E2111 – 12

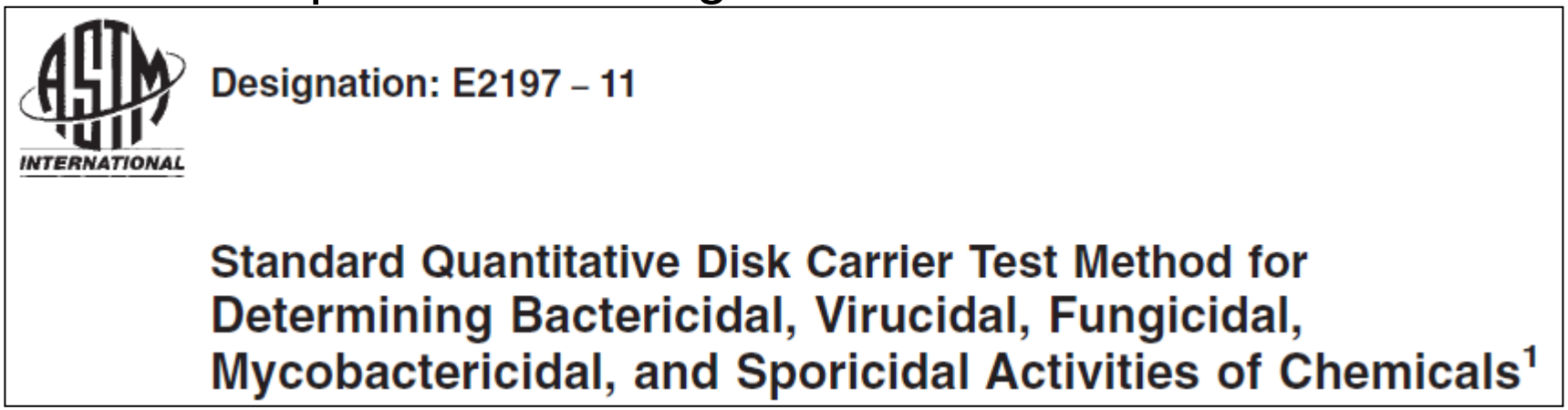
Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemicals[1]

Testing Methods

Uses 1 cm stainless steel discs as carriers

Tests vegetative bacteria, viruses, fungi, mycobacteria, and bacterial spores.

Indicates representative organisms to be tested



Designation: E2197 – 11

Standard Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal, Mycobactericidal, and Sporicidal Activities of Chemicals[1]

Organisms

Staphylococcus aureus

Pseudomonas aeruginosa

Conidia of *Trichophyton mentagrophytes*

Candida albicans

Conidia of *Aspergillus niger*

Mycobacterium terrae

Spores of *Bacillus subtilis*

Spores of *Clostridium sporogenes*

Organisms

Adenovirus (large non-enveloped virus)

Hepatitis A (small non-enveloped virus)

Canine Parvovirus (small non-enveloped virus)

Feline Calicivirus (small non-enveloped virus – surrogate)

Human Rhinovirus (small non-enveloped virus)

Human Rotavirus (large non-enveloped virus)

Murine Norovirus (small non-enveloped virus – surrogate)

(Bae 2009, Park 2010)

Test

Inoculate disc with 10ul of organism grown with soil load (5% serum)

Add test liquid and allow contact time

Neutralize and elute survivors

Control disc has neutral fluid added

US Environmental Protection Agency
Office of Pesticide Programs

Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for Germicidal Spray Products as Disinfectants (GSPT): Testing of Staphylococcus aureus, Pseudomonas aeruginosa, and Salmonella enterica

AOAC 961.02

Glass carriers

Spray product onto inoculated glass carriers

Allow contact time

Neutralize and grow

Back to Health Canada

Do recommend testing at 87-90% of the labeled nominal active ingredient concentrations, or provide an explanation as to why not.

[2] As set out in section C.01.062(1) of the *Food and Drug Regulations,* "no manufacturer shall sell a drug in dosage form where the amount of any medicinal ingredient therein, determined using an acceptable method is (a) less than 90.0 per cent of the amount of the medicinal ingredient shown on the label".

Health Canada Santé Canada

Guidance document - Disinfectant drugs

January 2014

Batch Replication

Bactericide, broad-spectrum virucide, sporicide and sanitizer claims

- 3 Batches per representative test organism

For fungicide, virucide and mycobactericide claims

- 2 batches per representative test organism

Towelettes

Can be tested by wiping inoculated surface with the appropriate wipe and chemistry, OR testing the juice from the towelette.

Designation: E2896 – 12

Standard Test Method for
Quantitative Petri Plate Method (QPM) for Determining the Effectiveness of Antimicrobial Towelettes[1]

Towelettes

New method using standard pressure

Also checks for transfer of organism to new surface

(Sattar 2015)

Designation: E2967 – 15

Standard Test Method for
Assessing the Ability of Pre-wetted Towelettes to Remove and Transfer Bacterial Contamination on Hard, Non-Porous Environmental Surfaces Using the Wiperator[1]

General Labeling

Thanks to Gord Platt!

FOR USE IN INDUSTRIAL & INSTITUTIONAL

Disinfectant Effective Against:

Bactericidal: Gram Negative, Gram Positive, **Virucidal:** Enveloped, Non-Enveloped, **Fungicidal:** Fungus, Mold

DISINFECTANT USE DIRECTIONS

HEAVILY SOILED SURFACES REQUIRE CLEANING PRIOR TO DISINFECTION

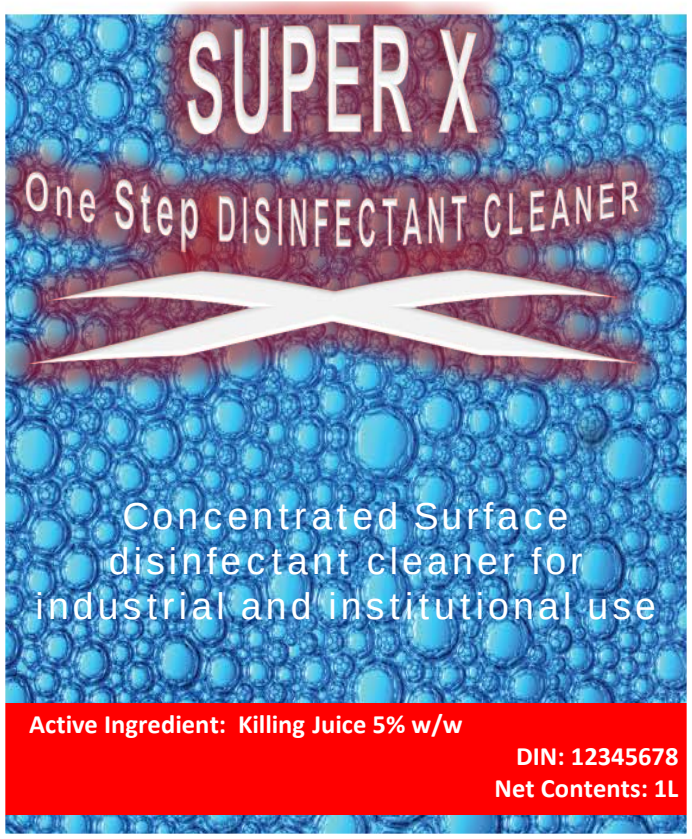
DISINFECTION OF NON-CRITICAL MEDICAL DEVICES, EQUIPMENT & NON-POROUS HARD SURFACES: coming in contact with intact skin such as the exterior of hemodialysis machines, stethoscopes, tabletops etc. Dilute 1:100. (Mix 1 part product with 99 parts tap water). Apply to surface with cloth or disposable wipe. Ensure surface remains wet for 7 minutes at 20°C.

Special Instructions for Cleaning and Decontamination of HIV (Human Immunodeficiency Virus) on objects and surfaces soiled with blood/body fluids. This product is intended for use against HIV only in those settings where the virus would be expected to be encountered, such as settings where contamination by blood or body fluids is likely.

Cleaning & Disinfecting Surfaces of Blood and Body Fluids: Gloves should be worn. Remove excess blood and fluid with absorbent materials. Clean contaminated area: Apply diluted 1:100 (mix 1 part product with 99 parts tap water) to surface, soak 45 seconds, wipe dry. Disinfect contaminated area: Apply diluted 1:100 to surface, allow surface to remain wet for 7 minutes at 20°C.

Personal Protection: Disposable gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

Disposal of Infectious Material: Products contaminated with blood or body fluids should be disposed of according to Federal, Provincial, and local regulations for infectious waste disposal.



CAUTION/ATTENTION

CORROSIVE/CORROSIF

ABC Chemicals

READ LABEL BEFORE USING

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS: KEEP OUT OF REACH OF CHILDREN. Corrosive material. May cause burns. Avoid contact with eyes and skin. Wear suitable protective clothing. Avoid contamination of food. Avoid storage at elevated temperatures. Do not mix with other cleaning or disinfecting products.

FIRST - AID: If in contact with eyes, flush immediately and thoroughly with water for 15 minutes. Call a physician. If in contact with skin, flush immediately with water. Wash thoroughly with soap and water. Obtain medical attention if irritation persists or develops. If ingested, do not induce vomiting. Call a physician or poison control center immediately. **TAKE CONTAINER, LABEL OR PRODUCT NAME AND DIN WITH YOU WHEN SEEKING MEDICAL ATTENTION.**

TOXICOLOGICAL INFORMATION: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DISPOSAL: For information on the disposal of unused, unwanted product and the clean up of spills, contact the Provincial Regulatory Agency or the Manufacturer. Triple rinse the container with water. Dispose of container in accordance with municipal, provincial and federal regulations. Do not reuse containers.

READ M.S.D.S. BEFORE USING PRODUCT.
MSDS available online at www.abcchem.com

SUPER X meets stability testing for up to 1 week after dilution with tap water.

Germicidal activity of this product was determined in accordance with the Canadian General Standards Board's standard CAN/CGSB-2.161-97

LOT No.: 12345
Expiry: 01/01/01

ABC Chemicals
Sesame, ST Canada S8S 8S8
1-800-888-8888

Bactericidal . Virucidal . Fungicidal

Product Name

Product Description & Intended Use

Active Ingredient

DIN and Net Contents

Precautionary Symbols / Wording

Product Efficacy

- Product Efficacy
- Precleaning Requirements
- Use & Dilution Instructions
- Bloodborne Pathogen Intended Use
- Bloodborne Pathogen Cleaning & Disinfection Instructions
- Bloodborne Pathogen PPE & Disposal of Infectious Material

FOR USE IN INDUSTRIAL & INSTITUTIONAL

Disinfectant Effective Against:

Bactericidal: Gram Negative, Gram Positive, **Virucidal:** Enveloped, Non-Enveloped, **Fungicidal:** Fungus, Mold

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Sealed Air Diversey Care

Precautionary Statements

PRECAUTIONARY STATEMENTS: KEEP OUT OF REACH OF CHILDREN. Corrosive material. May cause burns. Avoid contact with eyes and skin. Wear suitable protective clothing. Avoid contamination of food. Avoid storage at elevated temperatures. Do not mix with other cleaning or disinfecting products.

First Aid Requirements

FIRST - AID: If in contact with eyes, flush immediately and thoroughly with water for 15 minutes. Call a physician. If in contact with skin, flush immediately with water. Wash thoroughly with soap and water. Obtain medical attention if irritation persists or develops. If ingested, do not induce vomiting. Call a physician or poison control center immediately. **TAKE CONTAINER, LABEL OR PRODUCT NAME AND DIN WITH YOU WHEN SEEKING MEDICAL ATTENTION.**

Toxicological Information

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Disposal Instructions

DISPOSAL: For information on the disposal of unused, unwanted product and the clean up of spills, contact the Provincial Regulatory Agency or the Manufacturer. Triple rinse the container with water. Dispose of container in accordance with municipal, provincial and federal regulations. Do not reuse containers.

READ M.S.D.S. BEFORE USING PRODUCT. MSDS available online at www.abcchem.com

Product Stability & Germicidal Methodology

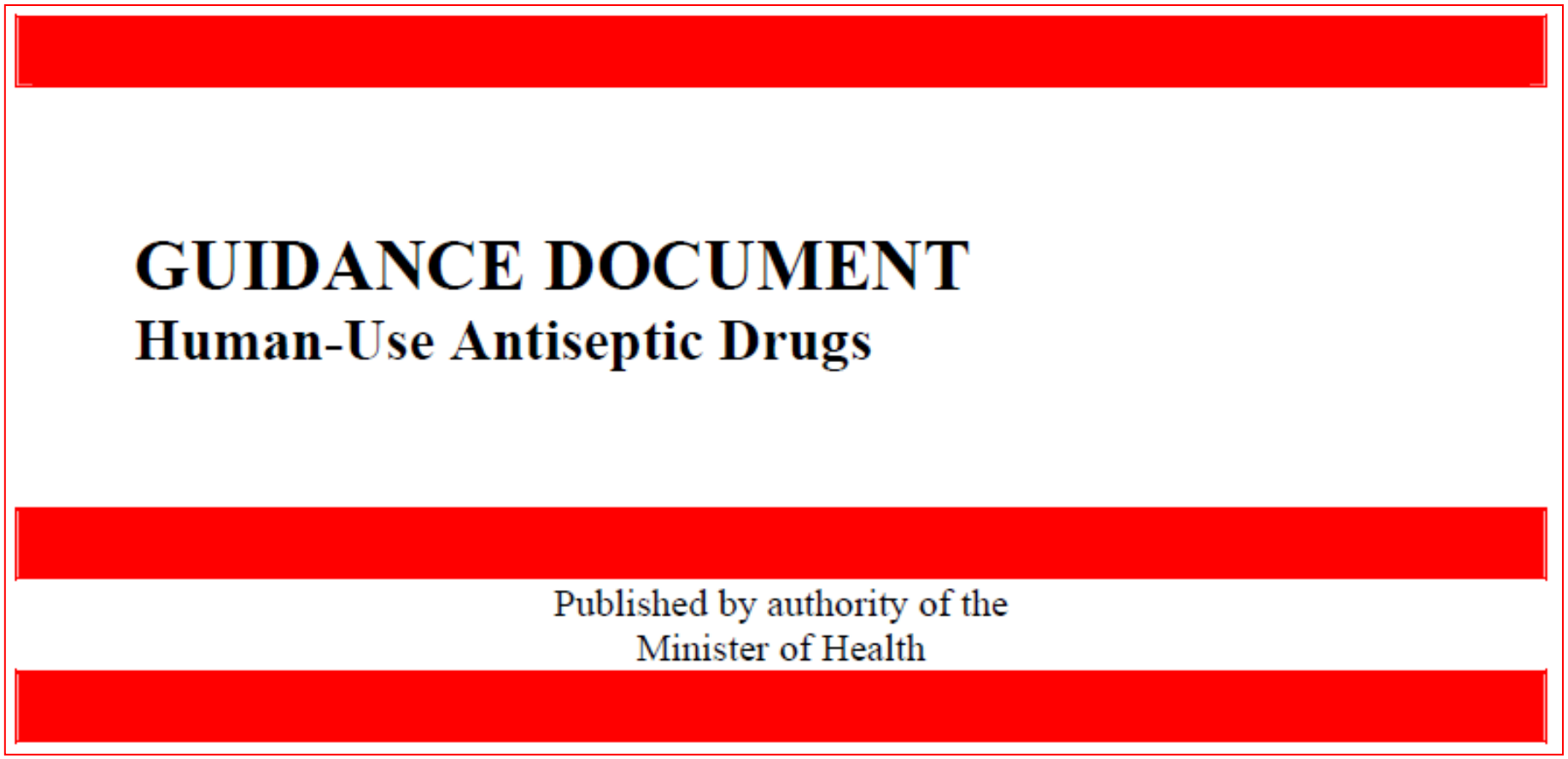
SUPER X meets stability testing for up to 1 week after dilution with tap water. Germicidal activity of this product was determined in accordance with the Canadian General Standards Board's standard CAN/CGSB-2.161-97

Manufacturer Contact Information

ABC Chemicals
Sesame, ST Canada S8S 8S8
1-800-888-8888

LOT No.: 12345
Expiry: 01/01/01

Hand Products



Types

Personal Use Products – Separate Document

- used by an individual in a domestic setting to reduce transient organisms on the skin

Commercial Use Products

- available to the general public for occasional use and are intended to reduce transient organisms on the skin in a commercial or institutional setting

Types

Professional Food Handler Use Products

- use by food handlers …in a commercial or institutional setting including food processing plants and also includes restaurants, retail supermarkets, and fast food outlets
- Full ingredients list and any residual on hands

Professional Healthcare Use Products

- …use… in a healthcare setting (such as hospitals, nursing homes, clinics, dental offices)

Professional Healthcare Use Products

- Professional Hygienic handrub
- Professional Hygienic handwash
- Surgical handrub
- Surgical handwash
- Patient preoperative skin preparations

Definition – Antiseptic Product

"An antiseptic product is considered to be one that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease"

- Food and Drug Regulations (FDR)
- Natural Health Products Regulations (NHPR)

Microorganisms include bacteria, yeast, fungi and viruses

- Not helminths, protozoan parasites

Definition

Washes – antiseptic product used with water

Rubs – antiseptic product used without water

Application

Applies to antiseptic skin products for human use that are intended for use in professional and commercial settings

Does not apply to human-use products for burn victims, first aid, or application to sites other than the skin (for example (e.g.) mucous membranes, catheter insertion, etc.)

Testing

In vitro – Test tube or lab conditions

- For surrogate and non-surrogate test organisms: one independent test report, which proves the antiseptic activity for a product
- One lot
- In Triplicate

Testing

In vivo – Human testing

- For non-surrogate test organisms: one independent test report…
- For surrogate test organisms: two independent test reports…
- … three separate lots of product
- Tests should be performed with sufficient subjects per tested product to satisfy the statistical criteria of the clinical trial design

No product will be accepted if its in vivo time-to-effect is >30 sec (rub) or > 60 sec (wash)

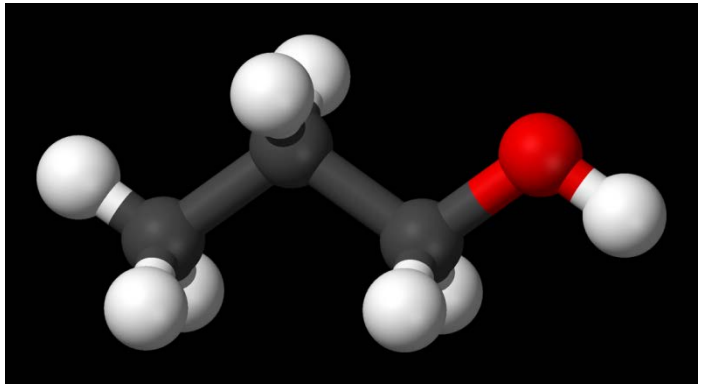
Test Standard

Personal use products: 2-propanol (isopropyl alcohol)

Professional use products: 1-propanol

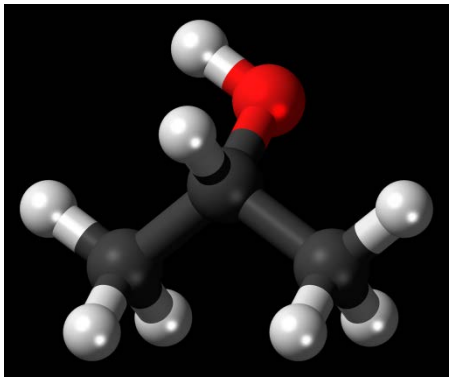
Use either EN or ASTM standard test methods (including testing for virus efficacy)

1-Propanol



$CH_3CH_2CH_2OH$

2-Propanol



CH3CHOHCH3

In Vitro

ASTM E 1052-96 … Viruses in Suspension.

EN 13624 Chemical disinfectants and antiseptics …fungicidal (phase 2, step 1)

EN 13727 Chemical disinfectants and antiseptics …bactericidal (phase 2, step 1)

EN 14348 Chemical disinfectants and antiseptics … mycobactericidal activity (phase 2, step 1)

EN 14476 Chemical disinfectants and antiseptics … virucidal (phase 2 step 1)

In Vivo – on Volunteers

EN 1499 Chemical disinfectants and antiseptics. Hygienic handwash. Test method and requirements (phase 2/step 2)

EN 1500 Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2)

ASTM E2276

ASTM E2011

EN 1500

12 – 15 subjects, intact skin on hands

Attempt to do all tests in the same day

Cross over – half use reference solution, half use test solution

Soft Soap (linseed oil, KOH, ethanol, distilled water) wash for 1 minute

In vivo Methodology

Inoculate hands up to mid-metacarpals for 5 seconds in $2x10^8$ – $2x10^9$ organisms in Tryptone soya broth (TSB)

Air dry for 3 minutes

Sample by rubbing finger tips in petri plate with TSB for one minute for pre-count level

3 mL 2-propanol and rub for 30 seconds (see method next slide!)

Repeat with 3mL for total 60 second contact time

5 second rinse with running tap water

In vivo Methodology

“This comprises 5 strokes backwards and forwards, palm to palm, right palm over left dorsum and left palm over right dorsum, palm to palm with fingers interlaced, back of fingers to opposing palms with fingers interlocked, rotational rubbing of right thumb clasped in left palm and left thumb clasped in right palm, rotational rubbing with clasped fingers of right hand in palm of left hand and clasped fingers of left hand in palm of right hand.”

In vivo Methodology

Use test product as per label instructions using above methods

Calculate pre and post levels

Calculate log reduction

Must be equal to or better than standard

Commercial Use Products

In Vitro

Testing not required for bacteria and mycobacteria

4 log for fungus and viruses (Polio, Adenovirus, Herpes simplex)

Commercial Use Products

In Vivo – 2 log

M. terrae, M. avium

Human Rotavirus, Rhinovirus, Hep A, Murine Norovirus, Adenovirus

S. marcescens, E. coli, St. aureus, St. epidermidis

Candida albicans, Aspergillus niger

Professional Food Handler

Beyond the scope of this presentation

In vitro tests more food poisoning organisms (Listeria, Campylobacter, Salmonella, Shigella, Staph, etc.)

Professional Healthcare Use

“Healthcare settings typically exhibit a higher presence of transient and/or nosocomial organisms than domestic or other commercial institutions. As such, there is an inherently higher safety risk to health if the product is not effective.”

Prof. Use – In Vitro – 5 log

Acinetobacter spp., *Bacteroides fragilis, Enterococcus faecium, Enterococcus hirae, Escherichia coli* K 12, *Haemophilus influenza, Klebsiella* spp., including *Klebsiella pneumoniae, Micrococcus luteus, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saprophyticus, Streptococcus pneumoniae, Streptococcus pyogenes*

Prof. Use – In Vitro – 5 log

Acinetobacter spp., *Bacteroides fragilis*, *Enterococcus faecium*, *Enterococcus hirae*, *Escherichia coli* K 12, *Haemophilus influenza*, *Klebsiella* spp., including *Klebsiella pneumoniae*, *Micrococcus luteus*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus saprophyticus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*

Prof. Use – In Vitro – 5 log

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Prof. Use – In vitro – 4 log

Adenovirus, Hepatitis A, Hepatitis B virus (surrogate Duck), Hepatitis C virus (surrogate Bovine Viral Diarrhea virus), Herpes simplex type 1&2, Influenza A&B virus, Murine Norovirus, Papovavirus, Polio virus type 1, Respiratory syncytial virus, Rhinovirus, Rotavirus

Prof. Use – In vitro – 4 log

Adenovirus, Hepatitis A, Hepatitis B virus (surrogate Duck), Hepatitis C virus (surrogate Bovine Viral Diarrhea virus), Herpes simplex type 1&2, Influenza A&B virus, Murine Norovirus, Papovavirus, Polio virus type 1, Respiratory syncytial virus, Rhinovirus, Rotavirus

Prof. Use - In vivo

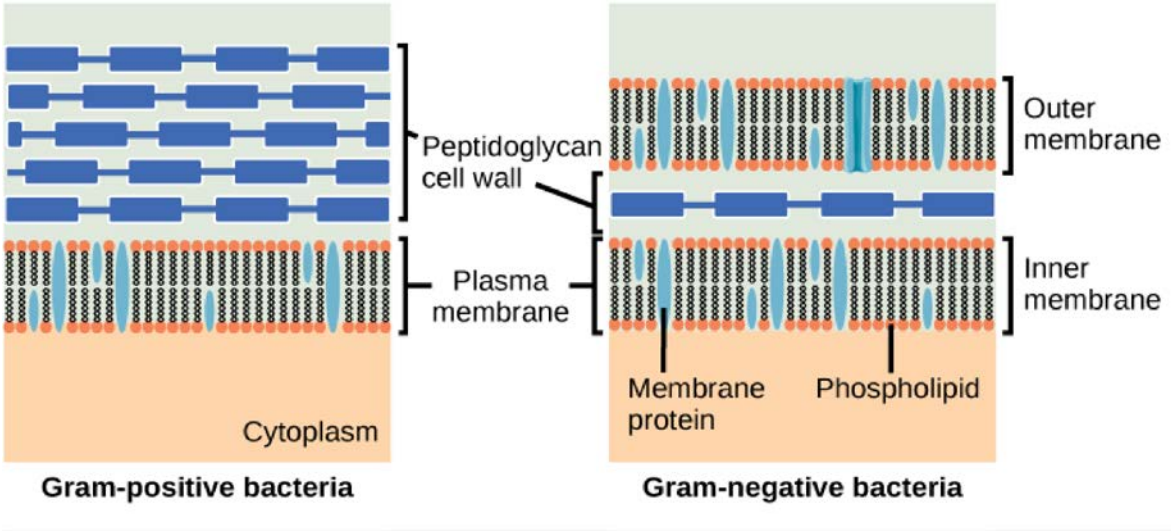
S. marcesens, E. coli, Mycobacteria sp. – 3 log

Candida albicans, *A. niger*, Rotavirus, Rhinovirus, Hepatitis A, Murine Norovirus, Adenovirus – 2 log

Summary

Extensive process required for new or updated products to be brought to market in Canada

From a microbiology perspective, curious use of organisms!



Summary

Does the extent of the testing make sense?

Financial impact on industry – hence to consumers

Questions?

Links/References

Guidance document - Disinfectant drugs

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disinfectant-drugs-final-eng.pdf (Accessed 20170212)

Guidance document - Management of Disinfectant Drug Applications

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/mdda-gpdd-eng.phpl (Accessed 20170212)

Guidance Document - Safety and efficacy requirements for hard surface disinfectant drugs

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/disinfect-desinfect/hard-surface-surfaces-dures-eng.pdf (Accessed 20170212)

Links/References

Guidance Document Human-Use Antiseptic Drugs

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.pdf

Guidance Document Antiseptic Skin Cleansers Domestic/Personal Use

http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=antiseptic_antiseptique

Sattar SA, et al. Disinfectant wipes are appropriate to control microbial bioburden from surfaces: use of a new ASTM standard test protocol to demonstrate efficacy. J Hosp Infect 2015;91:319-25. http://dx.doi.org/10.1016/j.jhin.2015.08.026

Links/References

Bae J, et al. Evaluation of Murine Norovirus, Feline Calicivirus, Poliovirus, and MS2 as Surrogates for Human Norovirus in a Model of Viral Persistence in Surface Water and Groundwater. App Environ Microbiol 2008;74(2):477-84.

Park GW et al. Comparative Efficacy of Seven Hand Sanitizers against Murine Norovirus, Feline Calicivirus, and GII.4 Norovirus. J Food Protect 2010;73(12):2232-8