

Search & Destroy:

What does all the fine print mean?

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Disinfectant History

- Over 8000 disinfectants registered in North America
- 95% are formulations based on chemistries that are over half a century old
 - Phenol
 - Quats
 - Alcohol
 - Aldehydes
- **Not patentable = No Novelty!**

Disinfectant Future

- Emerging technologies are focusing on Non-Halogen based oxidizers
 - Hydrogen Peroxide
 - Paracetic Acid
 - Organic Peroxides
 - Potassium or Sodium Percarbonate
- Sustainable, Novel = Patentable!

Disinfectants

vs

Antibiotics



Prevention versus Cure

Disinfectants

- Utilization of effective products and protocols
- Broad-spectrum kill in rapid contact time
- Hardier organisms require increase in chemical concentration & contact time
- Mixture of actives to improve efficacy or overcome resistance

Antibiotics

- Targeted initially, specific treatment regimen
- Development of Broad-spectrum antibiotics
- Dependent on disease/infection may require higher doses & length of treatment
- Resistance has led to the use of “cocktails”

Disinfectant Compatibility

- With antibiotic use it's called “SIDE EFFECTS”
- Disinfectants are unrealistically held accountable to be 100%:
 - Effective (Spectrum of Kill)
 - Rapid
 - Minimal impact to Health and Environment
 - Compatible with Everything
- Deal with the side effects of compatibility in the same way we deal with Antibiotic side effects

What does this mean to Infection Control?

- Must do away with the 1 pill fits all philosophy
- Development of disinfectants do not differ greatly from development of antibiotics
 - Minimize impact by optimizing results
 - Target Organism and/or body site
 - Minimize Side Effects

Who Wants to Register a Disinfectant?

What it takes to register a disinfectant


- Research and Development
 - Developing a formulation based on specified criteria
 - Use of legacy chemistries & formulations
 - Dual actives mixing different legacy chemistries
 - Development of something novel and patentable
- Data Generation
 - Once formulation is established everyone is on the same page (Efficacy, Toxicity, Chemistry)
- Submission
 - “Me-To” Registration can have a DIN in 45 days
 - New Registration of Novel product takes 255 days
- Commercialization

What does it take to develop a disinfectant?

- Legacy chemistries (Chlorine, Alcohol, Phenols, Quaternary Ammonium Compounds) have been on the market for close to half a decade
- Understood limitations such as narrow spectrum of kill, unrealistic contact times, occupation health & environment issues as well as compatibility issues
- Registration Bodies have developed Product Monographs that have established In-Use Solution Concentrations, Claims, Contact Times (10-minutes), Warnings & First Aid Information
- No novelty – ANYONE could bring a product to market in a matter of months with very little cost

What does it take to develop a disinfectant?

- Peracetic acid, hydrogen peroxide and organic peroxides have been identified as the next generation chemistries by the scientific community
- These novel, patentable chemistries address the many holes of legacy products but the complexity of formulation is high and take years and millions of dollars in R&D
- Improvements to spectrum of kill, realistic contact times, improved occupational health & environmental sustainability

 Health Canada Santé Canada

GUIDANCE DOCUMENT
Disinfectant Drugs

Published by authority of the
Minister of Health

Date Adopted	1999/04/20
Revised Date	2007/08/15
Effective Date	2007/10/29

Health Products and Food Branch

**The “Bible”
for
Registration
of
Disinfectants
in
Canada**

Submission Requirements

- Broken into three (3) distinct categories
 - Microbial Efficacy Data
 - Safety (Toxicology) Data
 - Quality (Chemistry) Data

Microbial Efficacy Data

- Bactericidal, Virucidal, Fungicidal, Mycobactericidal, Sporicidal
- Label claims will vary between manufacturers, between disinfectant chemistry or application
- Hospital Grade Disinfectants (Hard Non-Porous Surface) at minimum must be tested against *Salmonella enterica* (previously referred to as *S. choleraesuis*), *Pseudomonas aeruginosa* and *Staphylococcus aureus*
- High Level Disinfectants (Medical Device & Instruments) must be tested for efficacy against *Mycobacteria* spp, *Bacillus subtilis* and *Clostridium sporogenes*

Safety (Toxicology) Data

- Acute Oral Toxicity
 - Predicts the possible hazards from accidental ingestion. Results are report as LD₅₀ (median lethal dose) estimating the amount of the substance that is lethal in 50% of the test population. The oral LD₅₀ value is used to classify the tested product for precautionary labelling of end-use products.

Safety (Toxicology) Data

- Acute Inhalation Toxicity
 - Predicts the possible toxicity potential from exposure of the disinfectant through inhalation. Results are reported as LC₅₀ (median lethal concentration) estimating the concentration of the substance that is lethal to 50% of the test animals. The acute inhalation LC₅₀ value is used to classify the testing product for precautionary labelling of end-use products.

Safety (Toxicology) Data

- Acute Dermal Toxicity
 - Predicts the systemic toxicity potential and relative skin irritancy from a single dose exposure of the skin to the disinfectants. Results are reported as LD₅₀ (median lethal dose) estimating the amount of the substance that is lethal in 50% of the animals tested. The Dermal Toxicity LD₅₀ value is used to classify the tested product for precautionary labelling of end-use products.

Safety (Toxicology) Data

- Skin Sensitization
 - Predicts the sensitizing potential from exposure of the skin to disinfectants. The substance to be tested is applied on three (3) consecutive days. Using the Local Lymph Node Assay (LLNA) chemicals are classified as contact allergens if they elicit, at one or more test concentrations, a three-fold or greater in draining lymph node cell proliferation as compared to vehicle controls (i.e. olive oil). The Stimulation Index value is used for precautionary labelling of end-use products.

Safety (Toxicology) Data

- Acute Dermal Irritation
 - Predicts the possible hazards from exposure of the skin to the disinfectants. The skin irritation and/or corrosion effects, if any, are noted using the Draize System for Erythema, Eschar and Oedema Formation and used for precautionary labelling of end-use products.

Safety (Toxicology) Data

- Acute Eye Irritation
 - Predicts the possible hazards from accidental exposure of disinfectants to the eyes. The eye irritation and/or corrosion effects, if any, are used for precautionary labelling of end-use products. Results are based on determining the affects of exposure of the chemical on the Cornea, Iris and Conjunctivae (lids and nictitating membranes).

Quality (Chemistry) Data

- Product Formula
 - List of ingredients and concentrations
- Raw Material Specifications
- Product Specification and C of A
 - Physical state
 - Colour
 - pH
 - Viscosity
 - Density
- Primary Packaging Material Specifications

Quality (Chemistry) Data

- Long Term Stability Data
 - Accelerated Stability can be submitted initially with commitment to complete long term studies upon commercializing the product
- Reference of Test Methods used to generate the quality data
- Draft of the Product Label
- Product MSDS

Disinfectant Classification

Do current infection prevention and control definitions align with registration requirements?

What is a Disinfectant?

- The term “disinfectant” as defined and interpreted by the Therapeutic Product Directorate (TPD) Guidance Document is considered to include bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants, or any combination of these
- An agent that is capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects
 - Hard Surface Disinfectant specifies hard, non-porous inanimate surfaces or inanimate objects

Levels of Risk

Critical Items :

Instruments and devices that enter sterile tissues, including the vascular system. i.e. surgical instruments

Semi-Critical Items:

Devices that come in contact with non-intact skin or mucous membranes but ordinarily do not penetrate them. i.e. Endoscopes

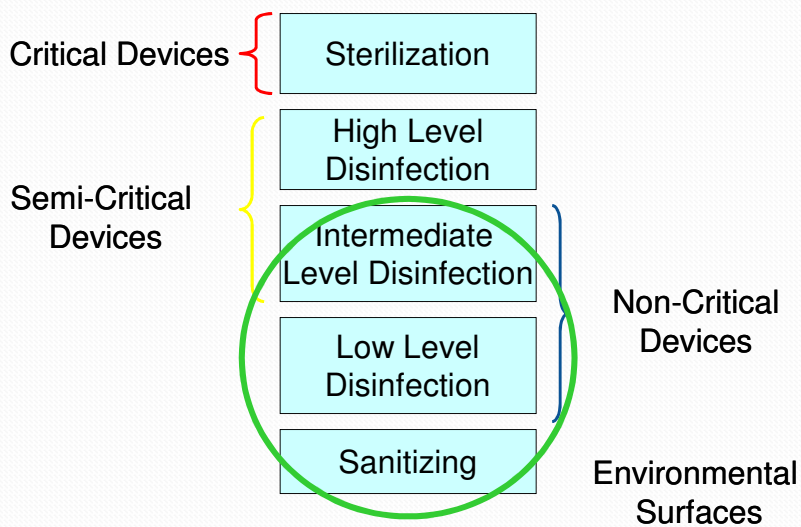
Non-Critical Items:

Those items that either touch only intact skin but not mucous membranes or do not directly touch the patient. i.e. Bed pans, BP Cuffs, etc.

Environmental Surfaces:

High Touch Surfaces and Housekeeping Surfaces

Process for Choosing a Disinfectant



Definition: *Sanitize*

- Infection Control Guidelines refers to sanitizing as the process that reduces bacteria on an inanimate object to a safe level.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
Sanitizer		√				

Definition: *Sanitize*

- TPD refers to sanitizing as the process that reduces the level of microorganisms present by significant numbers, or to acceptable levels established by federal or provincial health authorities.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
Sanitizer		3 log (99.9%)*				

*Food Contact Sanitizer requires 5 Log or 99.999%

Definition: *Low Level Disinfection*

- Infection Control Guidelines refers to this as the level of disinfection required when processing non-critical items or some environmental surfaces and kills most vegetative bacteria and some fungi as well as enveloped viruses but not mycobacteria or bacterial spores.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
LLD	√	√	√			

Definition: *Low Level Disinfection (LLD)*

- Therapeutic Product Directorate definition specifies a product that kills pathogenic & potentially pathogenic microorganisms on hard non-porous surfaces or inanimate objects when used according to labeling
- Should demonstrate efficacy against *Salmonella*, *Staphylococcus* and *Pseudomonas*

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
LLD	3 log (99.9%)	6 log (99.9999%)	5 log (99.999%)	3 log (99.9%)		

Definition: *Intermediate Level Disinfection (ILD)*

- Infection Control Guidelines refers to this as the level of disinfection that kills vegetative bacteria, mycobacteria, most viruses and most fungi but not resistant bacterial spores.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
ILD	✓	✓	✓	✓	✓	

Definition: *Intermediate Level Disinfection (IDL)*

- TPD defines ILD as a product that kills all microbial pathogens, except bacterial endospores, when used according to the label.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
ILD	3 log (99.9%)	6 log (99.9999%)	5 log (99.999%)	3 log (99.9%)	4 log (99.99%)	

Applications: LLD & ILD

- Ready-To-Use, Pre-moistened Wipes or Concentrate
 - Provision for shelf-life once diluted
- Used on HARD, NON-POROUS environmental surfaces or inanimate objects (non-critical devices)
 - Spray
 - Wipe
 - Mop & Bucket
- Not generally designed for use as a soaking agent
 - No reuse claims, therefore fresh solution to be used after each disinfection cycle

Definition: *High Level Disinfection (HLD)*

- Infection Control refers to this as the level of disinfection required when reprocessing semi-critical instruments. HLD destroys vegetative bacteria, mycobacteria, fungi, enveloped and non-enveloped viruses, but not necessarily bacterial spores.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
HLD	✓	✓	✓	✓	✓	✗

Definition: *High Level Disinfection (HLD)*

- TPD defines HLD as a disinfectant that kills all forms of microbial life except large number of bacterial endospores, when used according to the label.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
HLD			5 log (99.999%)		6 log (99.9999%)	6 log (99.9999%)

Definition: *Chemical Sterilization*

- Infection Control refers to this as the process that destroys all forms of microbial life including bacteria, viruses, spores and fungi.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
CS	√	√	√	√	√	√

Definition: *Chemical Sterilization*

- TPD moving towards the use of the term Critical Device Sporicide or Critical Sporicide
- A disinfectant which helps achieve sterilization.

	Enveloped Viruses	Vegetative Bacteria	Fungi	Non-Enveloped Viruses	Mycobacteria	Spores
CS			5 log (99.999%)		6 log (99.9999%)	6 log (99.9999%)

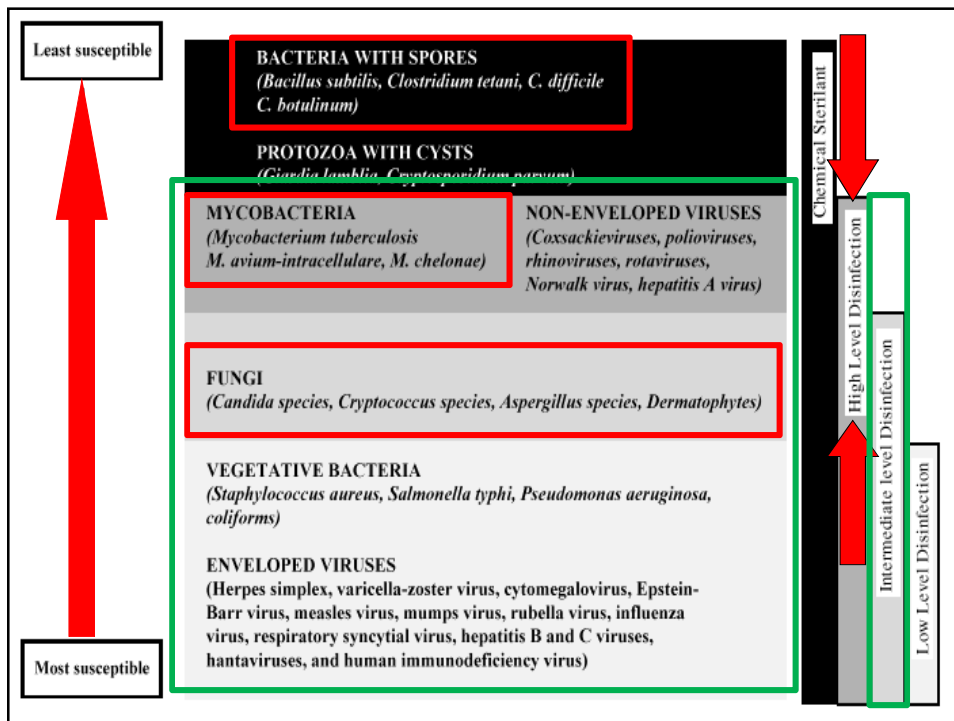
Application: HLD & Critical Sporicide

- Generally Ready-To-Use, some may require activation
 - Must have sporicidal activity in no longer than 10 hours
 - Sporicidal contact time does not have to be listed on label if product is not claiming to be a Critical Sporicide
- Used as an instrument soaking agent
 - Semi-Critical and Critical Devices
 - Provision for Re-Use time (ie. 14, 21, 28 days)
 - Provision for rinsing requirements
- Not designed to be used for disinfection of hard, non-porous environmental surfaces or non-critical medical devices
 - Do not spray or wipe

Microbial Kill Summary

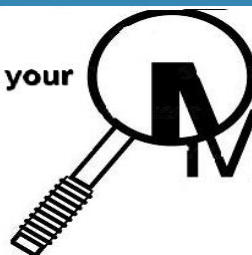
	Sanitizers*	LLD	ILD	HLD	CS
Enveloped Viruses		3 Log / (99.9%)	3 Log (99.9%)		
Vegetative Bacteria	3 Log / (99.9%)	6 Log (99.9999%)	6 Log (99.9999%)		
Fungi		5 Log (99.999%)	5 Log (99.999%)	5 Log (99.999%)	5 Log (99.999%)
Non-Enveloped Viruses		3 Log (99.9%)	3 Log (99.9%)		
Mycobacteria			4 Log (99.99%)	6 Log (99.9999%)	6 Log (99.9999%)
Spores				6 Log (99.9999%)	6 Log (99.9999%)

*Food Contact Sanitizer requires 5 Log or 99.999%



Understanding the Label

Get out your



magnifying glass

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.



**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 of 200 ppm hardness.

Germicidal activity of this product was determined in
 accordance with the Canadian General Standards Board's
 standard CAN/CSB-2:161-97

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

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



CAUTION/ATTENTION
READ LABEL BEFORE USING
KEEP OUT OF REACH OF CHILDREN

**ABC
 Chemicals**

Bactericidal . Virucidal . Fungicidal

TPD: Disinfectant Drugs

- Clearly outlines the requirements of what must be included on a label
 - DIN must be on the main panel
 - Name of Product & Manufacturer
 - Active Ingredients
 - Product description and Intended Use
 - Net contents
 - Precautionary symbols and cautionary statements
 - May find Product Efficacy and contact time information

TPD: Disinfectant Drugs

- Label requirements continued:
 - Product Efficacy, may list specific organisms
 - Pre-cleaning or cleaning requirements
 - Directions for Use
 - Specific directions for preparing in-use dilution including ratios or metric units
 - Contact Times and Temperature
 - Directions for Use for intended use against bloodborne pathogens
 - Reference to PPE
 - Directions for disposal of infectious waste

TPD: Disinfectant Drugs

- Label requirements continued:
 - Precautionary Statements
 - First Aid Requirements
 - Toxicological Information
 - Disposal Information
 - MSDS Reference
 - Product Stability and Germicidal Efficacy methodology
 - Lot Number and Product Expiry
 - Manufacturer Contact Information
 - Rinse procedures (as required by product usage)

References

- Guidance Document Disinfectant Drugs, Health Canada, October 2007
- Infection Control Guidelines: Hand Washing, Cleaning, Disinfection and Sterilization in Health Care, Health Canada. Dec 1998, Vol 24S8
- Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings, PIDAC, April 2006
- Guidelines for Environmental Infection Control in Healthcare Facilities, CDC. MMWR June 2003, Vol 52, No RR-10
- Rutala WA. APIC Guideline for Selection and Use of Disinfectants AJIC 1990;17(2) 99-117



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Experts in Chemical Disinfection for
Infection Control

