Disinfectants and sanitizers for use on food contact surfaces

Colette Gaulin, Mê-Linh Lê, Mona Shum, Daniel Fong

Summary

- Health Canada has approved the sale of disinfectants for food premises which contain chlorine compounds (e.g., bleach), peroxide and peroxyacid mixtures, carboxylic acids, quaternary ammonium compounds, acid anionic, and iodine compounds for use on food-contact surfaces.

- Disinfectants for use in food premises must have a drug identification number (DIN) and meet criteria, including those regarding antimicrobial efficacy, stipulated in the Health Canada document Guidance Document: Disinfectant Drugs. Products are evaluated by the Therapeutic Products Directorate (TPD) of Health Canada. Not all disinfectants are appropriate for use on food contact surfaces (e.g., toxic residues may be left). Product labels specify the intended/appropriate use of the disinfectant and should be read before use.

- Food contact sanitizers are regulated by the Bureau of Chemical Safety (BCS), Food Directorate, and Health Canada. The BCS determines the maximum residue levels that remain on food products after use and, if acceptable, the Canadian Food Inspection Agency (CFIA) issues a No Objection Letter for these products. Only food contact sanitizers that have disinfectant claims (such as bactericidal, virucidal) require a DIN.

- Important considerations when choosing a sanitizer for food contact surfaces include: effectiveness at reducing microbial contamination in specific conditions, cost, ease of application, need for rinsing, toxic/irritating properties, and compatibility with locally available water.

- For sanitizers to be effective, proper cleaning and rinsing must be completed before sanitizers are applied.

- Products such as tea tree oil, baking soda, vinegar, electrolyzed water, microfibre cloths, ozone, and silver compounds are not registered disinfectants for food premises, according to the Health Canada definition.

Introduction

There are numerous commercial products available for disinfecting and sanitizing surfaces in food premises, such as restaurants or processing plants. This document reviews the criteria for food-contact surface sanitizers and describes
active ingredients that have been proven effective for disinfecting and sanitizing food contact surfaces. This document is intended for food safety inspectors and auditors who may review the types and usage of sanitizers in food premises.

A food contact surface is defined by the Canadian Food Inspection Agency as any equipment or utensil which normally comes in contact with the food product or surfaces normally in contact with the product. Health Canada distinguishes between cleaners, disinfectants, food contact sanitizers, and sterilants (see Appendix A for definitions).

As the intended use and toxicological risks are different, disinfectants used on non-food contact surfaces (e.g., environmental surfaces, medical devices) are regulated differently than those used on food contact surfaces. Labelling should always be read before using disinfectants, as they specify the intended uses that are appropriate for the product. Food contact sanitizers are regulated by the Bureau of Chemical Safety, Food Directorate, and Health Canada; aspects of toxicity and safety are evaluated (e.g., residue levels). In collaboration with the Canadian Food Inspection Agency (CFIA), a No Objection Letter is issued for the product if, for example, the residue levels are evaluated as acceptable.

Although not all food contact sanitizers have disinfectant claims, those that do must have a Drug Identification Number (DIN) in order for the product to be authorized for sale in Canada. A unique DIN for the product is issued by Health Canada, once the product has been evaluated and meets the requirements outlined in the Health Canada document Guidance Document: Disinfectant Drugs (see Appendix B-D for the process of registration/approval).

General Information about Sanitizers

A sanitary environment is achieved by removing soil deposits and subsequently applying a sanitizer or disinfectant to reduce the number of residual microorganisms. Mechanical or physical cleaning (also called precleaning) is an important step in a sanitization program as some debris, such as organic matter, may inactivate or lead to decreased effectiveness of disinfectants. Prior to disinfection, the use of mechanical cleaning increases disinfectant efficacy, and in some cases, increases log reductions. Regular and effective cleaning can be more important than use of a disinfectant for reducing bacterial concentrations (e.g., cleaning and rinsing alone may achieve 2 to 3 log reduction).

Sanitization may be achieved through thermal, radioactive or chemical means. Chemical sanitizing is more frequently used in food production facilities than thermal or radiation techniques.

Operators must be careful not to mix or use multiple sanitizers at once. For instance, mixing ammonia and sodium hypochlorite solutions produce chloramines, while mixing sodium hypochlorite and acid solutions (e.g., vinegar) can produce chlorine gas.

According to the available literature, alternative antimicrobial products such as tea tree oil, baking soda, vinegar, silver, ozone, electrolyzed water, and microfibres have not met the Health Canada criteria for disinfectants in food premises. However, some may be listed as hard surface sanitizers on CFIA’s website, in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. A companion NCCEH document on alternative antimicrobial products will be available shortly.

There are a number of desired characteristics of sanitizers, but no single product will have all the characteristics listed below. Operators must decide on which ones are important to their own situations.
Desired Characteristics in a Sanitizer\textsuperscript{1,17}

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Desired Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of application</td>
<td>Low toxicity</td>
</tr>
<tr>
<td>Good penetrative power</td>
<td>Fast acting</td>
</tr>
<tr>
<td>Stability (long shelf life for concentrate)</td>
<td>No harmful or offensive odour</td>
</tr>
<tr>
<td>Compatibility with other chemicals and material of construction</td>
<td>Not adversely affected by organic matter</td>
</tr>
<tr>
<td>Demonstrate residual activity</td>
<td>Economy (cost-effective performance)</td>
</tr>
<tr>
<td></td>
<td>Active before and after dilution with hard water</td>
</tr>
<tr>
<td></td>
<td>Not persistent in the environment</td>
</tr>
</tbody>
</table>

### Resistance to Sanitizers

Growing concern over the development of resistance to certain therapeutic drugs has led to questions over microorganisms developing resistance to sanitizers. The three types of resistance that may occur are innate, apparent or acquired. As most sanitizers are non-specific, the development of resistance is mostly caused by innate factors,\textsuperscript{18} which are chromosomally controlled properties naturally associated with the organism. Potential mechanisms include:

- Impermeable cellular barriers preventing penetration of the sanitizer;
- Cellular efflux (mechanisms inside the cell pump compounds out);
- Lack of a biochemical target for antimicrobial attachment or microbial inactivation;
- Inactivation of antimicrobials by microbial enzymes.\textsuperscript{19,20}

While certain microorganisms have shown resistance to sanitizers (see Table 1), there is no evidence that the proper use of sanitizers in a food facility will cause resistant microorganisms to develop.\textsuperscript{19}

### Practical implications for operators

To ensure that operators are using the appropriate food-contact surface sanitizers, and using them properly to maximize effectiveness and reduce the chance of resistance occurring, PHIs should convey the following points:\textsuperscript{19}:

- If possible, use products with DIN that are approved by Health Canada for use in food premises. (To obtain information on disinfectants that have received authorization, visit this link: [http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp](http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp));
- As all food-contact surface sanitizers with DIN are effective at reducing bacteria, choose other characteristics that are desired (e.g., virucidal cost-effective, low toxicity, non-corrosive);
- Ensure surfaces are cleaned (i.e., organic matter and debris are removed) prior to sanitizing;
- Always use sanitizers according to manufacturer’s instructions and only for their intended purpose (i.e., use at recommended concentrations, temperature, pH, and contact time);
- Avoid mixing or using multiple sanitizers at once;
- Use mechanical force (i.e., scrubbing) to help eliminate biofilms;
- Determine whether rinsing needs to occur after application (e.g., see product label and manufacturer’s instructions). This step is concentration dependent (see Table 1 for concentrations above which rinsing is necessary);
- If resistance is discovered (by specific testing), use a disinfectant with a different active ingredient. Using higher concentrations of the same disinfectant is discouraged, as this could promote the emergence of resistant microbes.

### Evidence Gap

Although proper cleaning before sanitizing should reduce any risk of producing disinfection by-products, there is little information on whether the production of disinfection by-products is a problem in real-world situations, where surfaces may not always be cleaned properly.
Table 1 Characteristics of commonly used active ingredients for sanitizing food surfaces

<table>
<thead>
<tr>
<th>Sanitizer</th>
<th>Affected Microorganisms/Resistance or Limitations</th>
<th>Sanitizing/Rinse Concentration</th>
<th>Toxicity</th>
<th>Stability</th>
<th>Odour</th>
<th>Residual Activity</th>
<th>Hard Water Affects</th>
<th>Organic Matter Affects</th>
<th>Corrosive (metals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorine compounds</td>
<td>Bacteria, fungi, viruses</td>
<td>50 to 500 ppm typical</td>
<td>Skin and respiratory irritant.</td>
<td>√</td>
<td>√</td>
<td>-</td>
<td>-</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>(most common: Calcium and sodium hypochlorites)</td>
<td>Spores: YES Biofilm: NO</td>
<td>Although 200 ppm is effective for numerous surfaces, 800 ppm is suggested for porous areas. Rinse @ ≥ 200 ppm</td>
<td>Burning pain, inflammation and blisters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resistance: Cryptosporidium&lt;sup&gt;27&lt;/sup&gt;, Giardia lamblia (less so)&lt;sup&gt;28&lt;/sup&gt;, Salmonella&lt;sup&gt;29&lt;/sup&gt;, Methicillin-resistant Staphylococcus aureus (MSRA)&lt;sup&gt;30&lt;/sup&gt;</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Mixtures of Peroxide and Peroxyacid (PAA)&lt;sup&gt;25,31&lt;/sup&gt;</td>
<td>Bacteria, fungi, viruses, Mycobacterium tuberculosis</td>
<td>50 to 350 ppm typical, generally used at 150 to 200 ppm</td>
<td>Depends on wetting agents. Highly corrosive and extremely hazardous to skin. Can cause blistering, itching, scaling, or skin burns.</td>
<td>√</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>Spores: YES Biofilm: YES</td>
<td>Rinse @ &gt; 300 ppm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resistance: Biofilms of Listeria monocytogenes (exposed for 40 min to the minimum inhibitory concentration)&lt;sup&gt;32&lt;/sup&gt;, Salmonella typhimurium, L. monocytogenes, Escherichia coli O157:H7 can become more acid resistant when exposed to mild acidic conditions&lt;sup&gt;33,34&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: The active ingredients listed (e.g., chlorine compounds) have all been broadly approved for use in sanitizer or disinfectant products by Health Canada.<sup>27</sup> [Table 5:7]
<table>
<thead>
<tr>
<th>Sanitizer</th>
<th>Affected Microorganisms/Resistance or Limitations</th>
<th>Sanitizing/Rinse Concentration</th>
<th>Toxicity</th>
<th>Stability</th>
<th>Odour</th>
<th>Residual Activity</th>
<th>Hard Water Affects</th>
<th>Organic Matter Affects</th>
<th>Corrosive (metals)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acid anionic sanitizers</strong>&lt;sup&gt;22,23,25&lt;/sup&gt;</td>
<td>Same as above</td>
<td>100 to 500 ppm typical Rinse @ &gt; 200 ppm</td>
<td>Same</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Carboxylic acid (fatty acid sanitizer)</strong>&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Same as above</td>
<td>70 to 1,500 ppm typical No rinse necessary</td>
<td>Same</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hydrogen Peroxide (H2O2)</strong>&lt;sup&gt;23,24,26&lt;/sup&gt;</td>
<td>Bacteria, viruses, fungi Legionella, E.coli, Influenza A and B, Pseudomonas, Campylobacter, Salmonella, MRSA, VRE Spores: YES Biofilm: No Resistance: L. monocytogenes in biofilm&lt;sup&gt;35&lt;/sup&gt;</td>
<td>Powder in 3% and 6% Rinse @ ≥ 1,100 ppm</td>
<td>Can cause skin irritation. ↓ w ↑ T Accel. H2O2 more stable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quaternary ammonium compounds (QUATS)</strong>&lt;sup&gt;22-25&lt;/sup&gt;</td>
<td>Various microorganisms. Effective against L. monocytogenes. More effective against vegetative bacteria Spores: NO Biofilm: YES Limitations: Limited effectiveness against most gram-negative bacteria except Salmonella and E. coli&lt;sup&gt;30,39,40&lt;/sup&gt; Cotton fibres and cellulose wipes can absorb some of the QUATS.&lt;sup&gt;31-43&lt;/sup&gt;</td>
<td>200 to 1,000 ppm typical Generally used at 200 ppm Rinse @ ≥ 200 ppm</td>
<td>Respiratory and skin irritant Excellent</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

* Accelerated hydrogen peroxide (sometimes known as stabilized hydrogen peroxide) is a patented blend of common ingredients (i.e., an acid with an anionic surfactant) that, when mixed with low levels of stabilized hydrogen peroxide, increases its germicidal potency significantly.<sup>36</sup> It shares many of the same characteristics as hydrogen peroxide (spectrum of activity, odour) but is non-toxic and only slightly corrosive to soft metals (i.e., it is ideally suited for use on stainless steel).<sup>37</sup> Although the exact mechanism is unknown the manufacturer has provided a multi-stage explanation of their best understanding of how AHP works.<sup>38</sup>
<table>
<thead>
<tr>
<th>Sanitizer</th>
<th>Affected Microorganisms/ Resistance or Limitations</th>
<th>Sanitizing/Rinse Concentration</th>
<th>Toxicity</th>
<th>Stability</th>
<th>Odour</th>
<th>Residual Activity</th>
<th>Hard Water Affects</th>
<th>Organic Matter Affects</th>
<th>Corrosive (metals)</th>
</tr>
</thead>
</table>
| **Iodophors**<sup>22,24,25,47,48</sup> | Variety of bacteria, fungi, viruses, and yeasts  
Spores: NO  
Biofilm: NO  
Resistance: General absence of resistance to povidone-iodine<sup>49</sup> and iodine,<sup>50</sup> although some resistance to methicillin-resistant S. aureus (MSRA) suggested<sup>30</sup> | 6.5 to 75 ppm typical Rinse @ ≥ 25 ppm | Depends on wetting agents. Iodophors may bleach skin or cause irritation | Varies with T | -     | -                | -                 | √                   | √                   |
|                  | Tightness of weave influences degree of absorption.<sup>45,46</sup>  
Soap and water can reduce effectiveness<sup>45,46</sup> |                                 |          |           |       |                  |                   |                     |                     |

Variety of bacteria, fungi, viruses, and yeasts

Spores: NO
Biofilm: NO

Resistance: General absence of resistance to povidone-iodine<sup>49</sup> and iodine,<sup>50</sup> although some resistance to methicillin-resistant S. aureus (MSRA) suggested<sup>30</sup>
Acknowledgements

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   http://www.epa.gov/opp00001/factsheets/antimic.htm
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   www.schiff-consulting.com/choosing.html


52. U.S. Environmental Protection Agency. Registration requirements for antimicrobial pesticide products and other pesticide regulatory changes; Proposed rule. Fed Regist. 1999;64(180).

Appendix A: Definitions

Health Canada distinguishes between cleaners, disinfectants, sanitizers, and sterilants using the following definitions. Although sanitizers and disinfectants may have similar efficacy, the standards and criteria used to test their efficacy claims differ.

Cleaners

Detergents or abrasive cleaners physically or chemically remove soil, dust, organic matter, or microorganisms. They are usually intended for specific areas (e.g., floors, walls, tables) and can be used on surfaces that come into contact with food. Mechanical or physical cleaning (also called precleaning) is an important step in a sanitization program. Some forms of debris, such as organic matter, may inactivate or lead to decreased effectiveness in several disinfectants, including alcohol, aldehyde, sodium hypochlorite (bleach), and quaternary ammonium (QUATS) compounds. The use of mechanical cleaning prior to disinfection increases disinfectant efficacy and, in some cases, increases log-reductions.1

Cleaners may remove significant numbers of microorganisms, but they do not kill or eliminate them. Additional agents are required to disinfect or sanitize the surface.51

Sanitizers

Sanitizers reduce, but do not necessarily eliminate, the number of microorganisms on surfaces they come into contact with.21 Sanitizers are ordinarily used by the food processing, food handling, preparation, and service industries.22

There are two types of sanitizers:

1. Food contact sanitizers, with disinfectant claims, are used on surfaces that come into contact with food. In order to be authorized for sale by Health Canada, the chemical must reduce microbial contamination of specific bacteria by 99.999% or 5 log in 30 seconds at 20°C.17,23,47,52 Food contact sanitizers with no disinfectant claims may only reduce bacteria by 99.9% within 5 minutes.

2. Non-food contact sanitizers are used on surfaces that do not come into contact with food. Health Canada specifies that the chemical must reduce microbial contamination by 99.9% (3 log) or more within 5 minutes at room temperature (around 20-22°C).17,24,53

Disinfectants

Broadly speaking, disinfectants include bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants or any combinations thereof. There are various levels of disinfectants (low, intermediate, and high) categorized by differing efficacy levels, which in turn depend on their intended use. Efficacy of disinfectants is based on statistical significance of killing test bacteria on carriers (e.g., 59/60 test tubes are negative for growth).

Sterilants

Sterilants destroy or eliminate all types of microorganisms, including bacterial spores. Sterilants must demonstrate absence of growth in test samples, or a 99.9999% (6 log) reduction.

Sterilants include specialized chemicals such as glutaraldehyde, formaldehyde, and peroxyacetic acid. Dry heat (use of dry-heat ovens) and moist heat (use of steam under pressure or autoclaving) are also used for sterilization.

Appendix B: Approval or Registration

Canada

Product Registration or Acceptance:

Depending on a product’s claims and intended use, sanitizers and disinfectants are registered for use in Canada by the Therapeutic Products Directorate (Health Canada), the Canadian Food Inspection Agency (CFIA) or the Pest Management Regulatory Agency (PMRA).

Therapeutic Products Directorate (Health Canada):

Hard-surface sanitizers (with disinfectant claims) and disinfectants with non-food contact sanitizer claims are regulated by the Therapeutic Products Directorate (TPD) and Health Canada, under the Food and Drugs Act. The TPD does not regulate products without disinfection claims (i.e., with sanitizer-only claims). Before a product is authorized for sale in Canada, the manufacturer must provide to the TPD “substantive scientific evidence of a product’s efficacy, safety, and quality,” as required by the Food and Drugs Act and Food and Drug Regulation. Once the TPD assesses a product’s efficacy, safety, and quality claims, it is given market authorization and a Drug Identification Number (DIN), which must be placed on the product’s label.

A DIN submission must include:

- an application form;
- a Drug Submission Certification (indicates compliance with Good Manufacturing Practices);
- complete labelling information (see below for information required on labels).

In addition, safety and efficacy data is required for disinfectant products, except those that meet all the criteria of an existing class monograph or labelling standard. Product manufacturers must have data on hand that establishes the safety of their product, including acute and chronic toxicity information. Once a disinfectant has been authorized by the TPD, a Notice of Decision that summarizes the scientific and benefit/risk-based decisions that led to authorization is made available to the public, through the pilot project Summary Basis of Decision (applies only to disinfectants approved through the New Drug Submission process).

In order to receive a DIN, manufacturers must comply with drug labelling standards. The product label must list:
• active ingredients and their concentrations;
• intended use of the product (e.g., in a food processing plant);
• type of product (e.g., disinfectant, fungicide, etc.);
• detailed guidelines for usage, including:
  o type of surface;
  o preparation;
  o mode of application;
  o contact time;
  o potential warnings.
• health and first aid information.

Certain claims, such as non-toxic, non-irritant, safe, non-caustic cannot appear on labels.²⁴

Manufacturers must also include written procedures on how to use a product, including the exact concentration required for maximum effectiveness.

Product users should adhere closely to instructions provided on the product label to determine the appropriate method of use and concentration, and to avoid potential health or safety hazards.⁶ The effectiveness of chemical disinfectants depends on the contact time, temperature, and concentration of the application. Users can search the Health Canada website to obtain information on disinfectants, including food contact sanitizers with disinfectant claims, via the link below:


**Canadian Food Inspection Agency (CFIA):**

Under their *Non-Food Chemical Program*, the CFIA works closely with the Bureau of Chemical Safety (BCS) to regulate sanitizers that come into direct contact with food (considered Incidental Additives) in federally registered food establishments.⁵⁶ A non-food chemical is any product used in a food preparation setting that is not intended to become part of the food product.

Applications submitted to the CFIA are usually referred to the BCS for evaluation of the chemical safety aspects of the product. The Bureau will assess and determine the maximum residue level (MRL) that remains on the food product after use. If considered acceptable, a *No Objection Letter* is issued and the product is added to CFIA’s list of accepted products. To submit a product to CFIA for acceptance, manufacturers must indicate a product’s name, intended function, CAS number, chemical(s) name, and % by weight. A sample label that includes all ingredients and directions for use is also required. Any product that makes a disinfectant claim must have a DIN from Health Canada.

The CFIA provides a database of products, including sanitizers and disinfectants, which are acceptable for use in establishments that operate under the authority of CFIA:


**Pest Management Regulatory Agency:**

Non-food contact sanitizers (e.g., disinfectants used in swimming pools, water purifiers) are regulated by the PMRA as pesticides and are granted a Pest Control Product (PCP) number.
In the U.S., products must meet certain efficacy requirements before being approved for sale. The Environmental Protection Agency’s guidelines, *Sanitizing Rinses* (for previously cleaned food-contact surfaces) and *Disinfectants for Use on Hard Surfaces*, outline product efficacy requirements.57

**Appendix C: Canadian General Standards Board CAN/CGSB-2.161.97: Efficacy requirements for hard-surface (food-contact) antimicrobial agents**

Health Canada advises manufacturers of disinfectants to consider CAN/CGSB-2.161.97 when designing test protocols to demonstrate efficacy. Data obtained using other methods will be considered, but Health Canada recommends that a discussion occur before a DIN application is submitted if an alternative methodology to CGSB-2.161-97 is used.

The CGSB defines disinfectants as an “antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces” (p. 2). Disinfectants that do not target a specific organism are simply known as bactericides. Disinfectants that come into contact with food-contact surfaces are low-level (hard-surface) disinfectants.

**Efficacy requirements for a low-level disinfectant:**

- Agent must be diluted with hard water (prepared according to AOAC 960.09 E and F; minimum hardness of 200 ppm as CaCO$_3$)
- Liquid samples (in accordance with CAN/CGSB-2.11, Method 1.3) are tested against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* using AOAC Use-dilution Methods 955.14, 955.15, and 964.02 with four modifications:
  - One sample must be verified for compliance with product specifications supplied by the manufacturer;
  - If there is a shelf life for the product, the samples tested must meet the applicable performance requirements at the end of the stated time period;
  - The times and temperatures used for testing must not be less than the times and temperatures advised in the product instructions;
  - From each of the three samples, sixty carriers for each of the three organisms must be tested.
### Appendix D: CAN/CGSB 2.161-97: Assessment of Efficacy of Antimicrobial Agents for Use on Environmental Surfaces and Medical Devices

<table>
<thead>
<tr>
<th>Definition</th>
<th>Efficacy Requirements</th>
<th>Efficacy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disinfectant</td>
<td>Antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces. If the disinfectant does not have specific target organisms noted on the label, it is considered a bactericide.</td>
<td>N/A</td>
</tr>
<tr>
<td>High-level disinfectant</td>
<td>Kills all microbial pathogens, except large numbers of bacterial endospores, when used in accordance with labelling.</td>
<td>Meet requirements of a sporicide and tuberculocide.</td>
</tr>
<tr>
<td>Low-level disinfectant</td>
<td>Kills all microbial pathogens, except large numbers of bacterial spores on inanimate surfaces.</td>
<td>Meet requirements of bactericide. If disinfectant makes claims on virucidal, fungicidal or tuberculocidal efficacy, the disinfectant must also meet those requirements.</td>
</tr>
<tr>
<td>Chemosterilant</td>
<td>Kills most vegetative bacteria and lipid or medium-sized viruses.</td>
<td>No growth shall be observed on any cultures.</td>
</tr>
<tr>
<td>Sporicide</td>
<td>Capable of destroying bacterial spores.</td>
<td>Not more than two cultures out of 120 shall show growth.</td>
</tr>
<tr>
<td>Virucide</td>
<td>Capable of destroying viruses.</td>
<td>Virus infectivity titre must be reduced by at least 3 log(10) beyond the level of cytotoxicity on all five test carriers.</td>
</tr>
<tr>
<td>Bactericide</td>
<td>Capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.</td>
<td>Not more than two cultures out of 60 shall show growth.</td>
</tr>
<tr>
<td>Germicide</td>
<td>Synonymous with disinfectant</td>
<td>See Disinfectant</td>
</tr>
<tr>
<td>Fungicide</td>
<td>Capable of destroying fungi and their spores.</td>
<td>No growth shall be observed.</td>
</tr>
<tr>
<td>Tuberculocide</td>
<td>Capable of destroying mycobacteria.</td>
<td>No growth shall be observed.</td>
</tr>
<tr>
<td>Mycobactericide</td>
<td>Synonymous with tuberculocide</td>
<td>See Tuberculocide</td>
</tr>
</tbody>
</table>

**Note:** See CAN/CGSB-2.161-97 for full details and testing and efficacy modifications.
Appendix E: Additional Resources

Health Canada:


The Health Canada Drug Product Database provides product and company information on disinfectants that have received authorization and are registered for sale in Canada: [http://www.hc-sc.gc.ca/dhp- mps/prodpharma/databasdon/index-eng.php](http://www.hc-sc.gc.ca/dhp- mps/prodpharma/databasdon/index-eng.php)


Canadian Food Inspection Agency (CFIA):

CFIA’s *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products* is a database listing products, including sanitizers and disinfectants, acceptable for use in establishments that operate under the authority of CFIA: [http://www.inspection.gc.ca/english/fssa/reference/refere.shtml](http://www.inspection.gc.ca/english/fssa/reference/refere.shtml)

CFIA guidelines for the development of a sanitation program, created as part of a broader food safety program: [http://www.inspection.gc.ca/english/fssa/fispoi/man/fimmii/chap3_4_be.shtml](http://www.inspection.gc.ca/english/fssa/fispoi/man/fimmii/chap3_4_be.shtml)

Environmental Protection Agency (U.S.):

EPA *Antimicrobial Policy & Guidance Documents* (includes relevant sections of the Code of Federal Regulations (as references), internal Guidance/Guidelines, Letters (containing guidance or relevant information), Protocols, Science Policy, and Templates (for registrants’ use) [http://www.epa.gov/oppad001/regpolicy.htm#Guidance](http://www.epa.gov/oppad001/regpolicy.htm#Guidance)

Efficacy data requirements for *Sanitizing Rinses* (for previously cleaned food-contact surfaces): [http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm](http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm)

Efficacy data requirements for *Disinfectants for Use on Hard Surfaces*: [http://www.epa.gov/oppad001/dis_tss_docs/dis-01.htm](http://www.epa.gov/oppad001/dis_tss_docs/dis-01.htm)

A listing of label requirements, efficacy data requirements, and standard test methods for a variety of sanitizers and disinfectants used by the Environmental Protection Agency (EPA) in the U.S.: [http://www.epa.gov/oppad001/sciencepolicy.htm](http://www.epa.gov/oppad001/sciencepolicy.htm)

Other:

The Hospitality Institute of Technology and Management provides instructional documents and discussion papers focused on hard surface sanitizing: [http://www.hi-tm.com/html/pubs_reports.html#facility](http://www.hi-tm.com/html/pubs_reports.html#facility)