

National Collaborating Centre for Environmental Health

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# Disinfectants and sanitizers for use on food contact surfaces

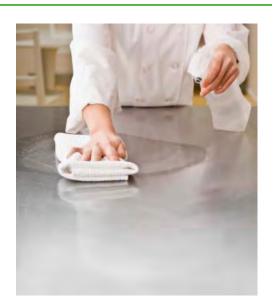
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# Summary

- Health Canada has approved the sale of disinfectants for food premises which contain chlorine compounds (e.g., bleach), peroxide and peroxyacid mixtures, carboxylic acids, guaternary 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
  - 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.

use of the disinfectant and should be

read before use.



**REVISED AUGUST 2011** 

- 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 foodcontact surface sanitizers and describes

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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.<sup>1</sup> 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 disinfectant efficacy, and in some cases, increases log reductions.<sup>1</sup> 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).<sup>2</sup>

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.<sup>3</sup>

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.<sup>4-16</sup> 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.

Ease of application	Low toxicity	Non-corrosive
Good penetrative power	Fast acting	No harmful or offensive odour
Stability (long shelf life for concentrate)	Not adversely affected by organic matter	Active before and after dilution with hard water
Compatibility with other chemicals and material of construction	Broad spectrum of activity towards gram-positive and gram-negative bacteria, fungi, and viruses	Not persistent in the environment
Demonstrate residual activity	Economy (cost- effective performance)	

#### Desired Characteristics in a Sanitizer<sup>1,17</sup>

## **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,<sup>18</sup> 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.<sup>19,20</sup>

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.<sup>19</sup>

# 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<sup>19</sup>:

- 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: <u>http://webprod.hc-sc.gc.ca/dpd-bdpp/indexeng.jsp</u>.);
- 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 byproducts 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

Sanitizer	Affected Microorganisms/ Resistance or Limitations <sup>19</sup>	Sanitizing/ Rinse Concentration	Toxicity	Stability	Odour	Residual Activity	Hard Water Affects	Organic Matter Affects	Corrosive (metals)
Chlorine compounds <sup>21-26</sup> (most common: Calcium and sodium hypochlorites)	Bacteria, fungi, viruses Spores: YES Biofilm: NO Resistance: <i>Cryptosporidium</i> , <sup>27</sup> <i>Giardia lamblia</i> (less so), <sup>28</sup> <i>Salmonella</i> <sup>29</sup> ; Methicillin-resistant <i>Staphylococcus</i> <i>aureus</i> (MSRA) <sup>30</sup>	50 to 500 ppm typical Although 200 ppm is effective for numerous surfaces, 800 ppm is suggested for porous areas. Rinse @ ≥ 200 ppm	Skin and respiratory irritant. Burning pain, inflammation and blisters	↓ w/ light, >60°C	~	1	-	V	1
<i>Mixtures of</i> <i>Peroxyacid</i> <i>(PAA)</i> <sup>25,31</sup>	Bacteria, fungi, viruses, <i>Mycobacterium</i> <i>tuberculosis</i> Spores: YES Biofilm: YES Resistance: Biofilms of <i>Listeria</i> <i>monocytogenes</i> (exposed for 40 min to the minimum inhibitory concentration) <sup>32</sup> <i>Salmonella</i> <i>typhimurium, L.</i> <i>monocytogenes,</i> <i>Escherichia coli</i> O157:H7 can become more acid resistant when exposed to mild acidic conditions <sup>33,34</sup>	50 to 350 ppm typical, generally used at 150 to 200 ppm Rinse @ > 300 ppm	Depends on wetting agents. Highly corrosive and extremely hazardous to skin. Can cause blistering, itching, scaling, or skin burns.	Excellent	√	-	-	-	√ some metals, mild and galvanized steel ↑ w/High T

\***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 [Table 5:7]</sup>

Sanitizer	Affected Microorganisms/ Resistance or Limitations <sup>19</sup>	Sanitizing/ Rinse Concentration	Toxicity	Stability	Odour	Residual Activity	Hard Water Affects	Organic Matter Affects	Corrosive (metals)
Acid anionic sanitizers <sup>22,23,25</sup>	Same as above	100 to 500 ppm typical Rinse @ > 200 ppm	Same						
<i>Carboxylic acid</i> (fatty acid sanitizer) <sup>23</sup>	Same as above	70 to 1,500 ppm typical No rinse necessary	Same						
Hydrogen Peroxide (H2O2) <sup>23,24,26</sup>	Bacteria, viruses, fungi Legionella, E.coli, Influenza A and B, Pseudomonas, Campylobacter, Salmonella, MRSA, VRE Spores: YES Biofilm: No Resistance: L. monocytogenes in biofilm <sup>35</sup>	Powder in 3% and 6% Rinse @ ≥ 1,100 ppm	Can cause skin irritation.	↓ w ↑ T Accel. H2O2 more stable <b>*</b>	-	-	1	?	N
Quaternary ammonium compounds (QUATS) <sup>22-25</sup>	Various microorganisms. Effective against <i>L.</i> <i>monocytogenes.</i> More effective against vegetative bacteria Spores: NO Biofilm: YES Limitations: Limited effectiveness against most gram- negative bacteria except <i>Salmonella</i> and <i>E. coli.</i> <sup>30,39,40</sup> Cotton fibres and cellulose wipes can absorb some of the QUATS. <sup>41-43</sup>	200 to 1.000 ppm typical Generally used at 200 ppm Rinse @ ≥ 200 ppm	Respiratory and skin irritant	Excellent	1	1	1	1	No

<sup>\*</sup> 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>

Sanitizer	Affected Microorganisms/ Resistance or Limitations <sup>19</sup>	Sanitizing/ Rinse Concentration	Toxicity	Stability	Odour	Residual Activity	Hard Water Affects	Organic Matter Affects	Corrosive (metals)
	Tightness of weave influences degree of absorption. <sup>44</sup> Soap and water can reduce effectiveness <sup>45,46</sup>								
lodophors <sup>22,24,25,47,48</sup>	Variety of bacteria, fungi, viruses, and yeasts Spores: NO Biofilm: NO	6.5 to 75 ppm typical Rinse @ ≥ 25 ppm	Depends on wetting agents. lodophors may bleach skin or cause irritation	Varies with T	-	-	-	V	√ stains silver
	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

We would like to thank the following individuals for their valuable input and review of the draft document: Nelson Fok, Graham Monda, Larry Mendes, Peter Stein, Sion Shyng, Normand Marriott, Bruce Gamage, April Gravelle, Jessica Pronto, and Ian Chisholm.

## References

1. Holah JT, Lavaud A, Peters W, Dye KA. Future techniques for disinfectant efficacy testing. Int Biodeterior Biodegradation. 1998;41(3-4):273-9.

2. Tebbutt GM. A microbiological study of various food premises with an assessment of cleaning and disinfection practices. J Hyg (Lond). 1984;93:365-75.

3. New Jersey Department of Health and Senior Services. Common cleaning products may be dangerous when mixed. Trenton, NJ: Div of Epid, Environ and Occup Health, Consumer and Environmental Health Services. Available from:

http://www.state.nj.us/health/eoh/cehsweb/bleach\_fs.pdf.

4. May J, Chan CH, King A, Williams L, French GL. Time-kill studies of tea tree oils on clinical isolates. J Antimicrob Chemother. 2000;45(5):639-43.

5. Carson CF, Hammer KA, Riley TV. Melaleuca alternifolia (tea tree) oil: A review of antimicrobial and other medicinal properties. Clin Microbiol Rev. 2006;19(1):50-62.

6. Rutala WA, Barbee SL, Aguiar NC, Sobsey MD, Weber DJ. Antimicrobial activity of home disinfectants and natural products against potential human pathogens. Infect Control Hosp Epidemiol. 2000;21(1):33-8.

7. Huang Y-R, Hung Y-C, Hsu S-Y, Huang Y-W, Hwang D-F. Application of electrolyzed water in the food industry. Food Control. 2008;19(4):329-45.

8. Brady MJ, Lisay CM, Yurkovetskiy AV, Sawan SP. Persistent silver disinfectant for the environmental control of pathogenic bacteria. Am J Infect Control. 2003;31(4):208-14.

9. Schuster A, Frank U, Daschner FD. Persistent silver disinfectant for the environment: myth and reality. Am J Infect Control. 2004;32(5):309-11.

10. Brady M, Sawan S. Reply. Am J Infect Control. 2004;32:309-11.

11. Lalla F, Dingle P, Cheong C. The antibacterial action of cloths and sanitizers and the use of environmental alternatives in food industries. J Environ Health. 2005;68(5):31-5.

12. Lalla F, Dingle P. The efficacy of cleaning products on food industry surfaces. J Environ Health. 2004;67(2):17-22.

13. Moore G, Griffith C. A laboratory evaluation of the decontamination properties of microfibre cloths. J Hosp Infect. 2006;64(4):379-85.

14. Warriner K. Efficacy of ozone hand wash relative to anti-bacterial soap and water. Guelph, ON: Univ of Guelph, Dept of Food Sciences; 2008.

15. Bodycote. Analysis report: Bacterial growth inhibition of ozone. Laval, QC: Bodycote Testing Group; 2007.

16. Khadre M, Yousef A. Decontamination of multilaminated aseptic food packaging material and stainless steel by ozone. J Food Safety. 2001;21(1):1-13.

17. Association of Official Analytical Chemists (AOAC). Germicidal and detergent sanitizing action of disinfectants. ATCC No. 11229. Method No. 960.09.

18. Russell AD. Plasmids and bacterial resistance to biocides. J Applied Microbiol. 1997;83:155-65.

19. Davidson P, Harrison M. Resistance and adaptation to food antimicrobials, sanitizers, and other process controls. Food Tech. 2002;56(11):69-79.

20. Bower CK, Daeschel MA. Resistance responses of microorganisms in food environments. Int J Food Microbiol. 1999;50(1-2):33-44.

21. U.S. Environmental Protection Agency. Antimicrobial pesticide products – Pesticides:Topical & chemical fact sheets. Washington, DC: EPA; 2004 [updated 2004 Dec 1; cited 2009 Nov 6]; Available from:

http://www.epa.gov/opp00001/factsheets/antimic.htm

22. Richter F, Cords B. Formulation of sanitizers and disinfectants. In: Seymour B, Block S, editors. Disinfection, sterilization and preservation. 5th ed. Philadelphia, PA: Lippincott Williams and Williams; 1999. p. 473-87.

23. Marriot N. Sanitition equipment. Principles of food sanitation. 5th ed. New York, NY: Springer; 2006. p. 158-89.

24. Bureau of Gastroenterology - Infection and Viral Diseases, Therapeutic Products Directorate. Release of final Health Canada document: "Guidance document: disinfectant drugs" - Drugs and health products. Ottawa, ON: Health Canada; 2007 [cited 2009 Aug 7]; Available from:

<u>http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-</u> demande/guide-ld/disinfect-desinfect/disinf\_desinf-eng.php

25. Schiff N. Choosing the proper sanitizer or disinfectant London, ON: Schiff Consulting; 1998: Available from: www.schiff-consulting.com/choosing.html.

26. U.S. Environmental Protection Agency. Hydrogen peroxide (Hydrogen dioxide) (000595) fact sheet – Pesticides: regulating pesticides. Washington, DC: EPA;

2008 [updated 2008 Oct 15; cited 2009 Nov 6]; Available from:

#### http://www.epa.gov/pesticides/biopesticides/ingredients/fact sheets/factsheet\_000595.htm.

27. Korich DG, Mead JR, Madore MS, Sinclair NA, Sterling CR. Effects of ozone, chlorine dioxide, chlorine, and monochloramine on Cryptosporidium parvum oocyst viability. Appl Environ Microbiol. 1990;56(5):1423-8.

28. U.S. Environmental Protection Agency. Alternative disinfectants and oxidants guidance manual. EPA 815-R-99-014. Washington, DC: EPA Office of Water; 1999. Available from:

http://www.epa.gov/OGWDW/mdbp/alternative\_disinfectants\_quidance.pdf.

29. Mokgatla RM, Gouws PA, Brözel VS. Mechanisms contributing to hypochlorous acid resistance of a *Salmonella* isolate from a poultry-processing plant. J Appl Microbiol. 2002;92(3):566-73.

30. Russell AD, Day MJ. Antibiotic and biocide resistance in bacteria. Microbios. 1996;85(342):45-65.

31. U.S. Environmental Protection Agency (EPA). R.E.D facts: peroxy compounds – Prevention, pesticides and toxic substances EPA-738-F-93-026. Washington, DC: EPA; 2008 [updated 1993 Dec; cited 2009 Nov 6]; Available from: www.epa.gov/oppsrrd1/REDs/factsheets/4072fact.pdf

32. Pickett EL, Murano EA. Sensitivity of *Listeria monocytogenes* to sanitizers after exposure to a chemical shock. J Food Prot. 1996;59:374-8.

33. Brudzinski L, Harrison MA. Influence of incubation conditions on survival and acid tolerance response of *Escherichia col* o157: h7 and non-o157:h7 isolates exposed to acetic acid. J Food Prot. 1998;61:542-6.

34. Buchanan RL, Edelson SG. Effect of pHdependent, stationary phase acid resistance on the thermal tolerance of Escherichia coli O157:H7. Food Microbiol. 1999;16(5):447-58.

35. Pan Y, Breidt F, Jr., Kathariou S. Resistance of Listeria monocytogenes biofilms to sanitizing agents in a simulated food processing environment. Appl Environ Microbiol. 2006;72(12):7711-7.

36. Omidbakhsh N. A new peroxide-based flexible endoscope-compatible high-level disinfectant. Am J Infect Control. 2006;34(9):571-7.

37. Omidbakhsh N, Kenny N. An accelerated hydrogen peroxide (AHP)-based fast-acting and reusable microbicide for manual disinfection of heat-sensitive semi-critical medical devices. Can J Infect Control. 2008;23(1):81-8.

38. Virox Technologies Inc. AHP versus alcohols. Oakville, ON: Virox Technologies Inc. Available from: http://www.virox.com/download.aspx?ItemInfoID=57

39. Holah JT, Taylor JH, Dawson DJ, Hall KE. Biocide use in the food industry and the disinfectant resistance of persistent strains of *Listeria monocytogenes* and *Escherichia coli*. J Appl Microbiol. 2002;92(S1):111S-20S.

40. Lematre J-P, Echchannaoui H, Michaut G, Divies C, Rousset A. Plasmid-mediated resistance to antimicrobial agents among Listeriae. J Food Prot. 1998;61:1459-64.

41. Goldsmith MT, Latlief MA, Friedl JL, Stuart LS. Adsorption of available chlorine and quaternary by cotton and wool fabrics from disinfecting solutions. Appl Microbiol. 1954;2(6):360-4.

42. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. Atlanta, GA: Centers for Disease Control; 2008; Available from:

http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection Nov 2008.pdf.

43. MacDougall K, Morris C. Optimizing disinfectant application in healthcare facilities. Infect Control Today [serial on the Internet]. 2006 [cited 2010 Mar 1]; June: Available from:

http://www.infectioncontroltoday.com/articles/399/66h23129 539034.html.

44. McNeil E, Greenstein M, Stuart LS, Goldsmith MT. Some problems involved in the use of quaternary ammonium compounds as fabric disinfectants. Appl Microbiol. 1960 May;8(3):156-9.

45. Sturm H, Konermann E, Aeschbacher R, Gradmann R. Quaternary ammonium compounds with bactericidal properties. Ind Eng Chem Res. 1953;45(1):186-8.

46. Tweedy JT. Healthcare hazard control and safety management. Bethesda , MD: HSP, Board of Certified Healthcare Safety Management; 1996.

47. Grab L, Bennett M. Methods of testing sanitizers and disinfectants. In: Seymour B, Block S, editors. Disinfection, sterilization and preservation. 5th ed. Philadelphia, PA: Lippincott Williams and Williams; 1999. p. 1373-82.

48. Davis J. lodophors as detergent-sterilizers. J Appl Microbiol. 1962;25(2):195-201.

49. Houang E, Gilmore O, Reid C, Shaw E. Absence of bacterial resistance to povidone iodine. J Clin Pathol. 1976;29(8):752-5.

50. Cooper RA. lodine revisited. Int Wound J. 2007 Jun;4(2):124-37.

51. Health Canada. Infection control guidelines: Hand washing, cleaning, disinfection and sterilization in health care. Can Commun Dis Rep. 1998 Dec;24 Suppl 8:i-xi, 1-55, i-xi, 1-7.

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

53. U.S. Environmental Protection Agency (EPA). Glossary of terms – Indoor air quality. Washington, DC: EPA; 2008 [updated 2008 Nov 25; cited 2009 Nov 6]; Available from: <u>http://www.epa.gov/iag/glossary.html</u>.

54. Health Canada. Trade memorandum: Efficacy data for antimicrobial products – Consumer product safety. 1980 [updated 1980 Oct 31; cited 2009 Nov 6]; Available from: http://www.hc-sc.gc.ca/cps-spc/pubs/pest/\_pol-guide/T-1-215/index-ena.php

Health Canada. Summary basis of decision (SBD) 55. - Drugs and health products. 2006 [updated 2006 Aug 21; cited 2009 Nov 6]; Available from: http://www.hcsc.gc.ca/dhp-mps/prodpharma/sbd-smd/index-eng.php

56. Health Canada. Guidelines for incidental additive submissions. 2005 [cited 2010 Jan 22]; Available from:

http://www.hc-sc.gc.ca/fn-an/legislation/guide-Id/quide incidental addit indirects-eng.php.

57. U.S. Environmental Protection Agency (EPA). Antimicrobial science policies disinfectant technical science section (DIS/TSS) - Pesticides: science and policy. Washington, DC: EPA; 2008 [updated 2008 Sept 23; cited 2009 Nov 6]; Available from:

http://www.epa.gov/oppad001/sciencepolicy.htm.

# **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.<sup>1</sup>

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.<sup>51</sup>

## **Sanitizers**

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

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.<sup>17,23,47,52</sup> 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).<sup>17,24,53</sup>

## Disinfectants

Broadly speaking, disinfectants include bactericides, fungicides, virucides, mycobactericides, tuberculocides, sporicides, sterilants or any combinations thereof.<sup>51</sup> 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.<sup>21,23-25,53</sup>

Sterilants must demonstrate absence of growth in test samples, or a 99.9999% (6 log) reduction.<sup>54</sup>

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.*<sup>54</sup> 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<sup>24</sup>:

- 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).<sup>55</sup>

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;
  - 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.<sup>24</sup>

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.<sup>6</sup> 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:

#### http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp.

#### 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.<sup>56</sup> 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:

http://www.inspection.gc.ca/english/fssa/reference/refere.shtml

#### 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.

## **United States**

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.<sup>57</sup>

## 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<sub>3</sub>)
- 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

	Definition	Efficacy Requirements	Efficacy Testing
Disinfectant	Ifectant 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. N		N/A
High-level disinfectant	Kills all microbial pathogens, except large numbers of bacterial endospores, when used in accordance with labelling.	Meet requirements of a sporicide and tuberculocide.	See Sporicide and Tuberculocide
Low-level disinfectant	Kills all microbial pathogens, except large numbers of bacterial spores on inanimate surfaces.	Meet requirements of bactericide. If disinfectant makes claims on virucidal, fungicidal or tuberculocidal efficacy, the disinfectant must also meet those requirements.	See Bactericide
Chemosterilant	Kills most vegetative bacteria and lipid or medium-sized viruses.	No growth shall be observed on any cultures.	Perform tests on viable spores of <i>Bacillus subtilis</i> and <i>Clostridium sporogenes</i> . Test conducted on 60 silk loops and 60 penicylinders per sample per organism. Typical microbial inoculation/bacterial load shall be 1 x 10(6) cfu/carrier.
Sporicide	Capable of destroying bacterial spores.	Not more than two cultures out of 120 shall show growth.	
Virucide	Capable of destroying viruses.	Virus infectivity titre must be reduced by at least 3 log(10) beyond the level of cytotoxicity on all five test carriers.	Samples tested against the poliovirus, Type 1
Bactericide	Capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.	Not more than two cultures out of 60 shall show growth.	Samples tested against Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa. 60 carriers tested for each of the 3 organisms from each of the 3 samples.
Germicide	Synonymous with disinfectant	See Disinfectant	
Fungicide	Capable of destroying fungi and their spores.	No growth shall be observed.	Samples tested against Trichophyton mentagrophytes
Tuberculocide	Capable of destroying mycobacteria.	No growth shall be observed	Samples tested against Mycobacterium bovis.
Mycobactericide	Synonymous with tuberculocide	See Tuberculocide	See Tuberculocide

Note: See CAN/CGSB-2.161-97 for full details and testing and efficacy modifications.

# **Appendix E: Additional Resources**

#### Health Canada:

Health Canada's 2007 *Guidance Document: Disinfectant Drugs* lays out policy and guidance on the regulation of disinfectant products in agreement with the Food and Drugs Act: <u>http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disinf\_desinf-eng.php</u>

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

Bureau of Chemical Safety, Food Directorate, Health Protection Branch, Health Canada: Guidelines for Incidental Additive Submissions: <u>http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/guide\_incidental\_addit\_indirects-eng.php</u>

## **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: <u>http://www.inspection.gc.ca/english/fssa/reference/refere.shtml</u>

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)

### **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) <u>http://www.epa.gov/oppad001/regpolicy.htm#Guidance</u>

Efficacy data requirements for Sanitizing Rinses (for previously cleaned food-contact surfaces): http://www.epa.gov/oppad001/dis\_tss\_docs/dis-04.htm

Efficacy data requirements for *Disinfectants for Use on Hard Surfaces*: <u>http://www.epa.gov/oppad001/dis\_tss\_docs/dis-01.htm</u>

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.: <a href="http://www.epa.gov/oppad001/sciencepolicy.htm">http://www.epa.gov/oppad001/sciencepolicy.htm</a>

#### **Other:**

The Hospitality Institute of Technology and Management provides instructional documents and discussion papers focused on hard surface sanitizing: <u>http://www.hi-tm.com/html/pubs\_reports.html#facility</u>

This document was produced by the National Collaborating Centre for Environmental Health at the British Columbia Centre for Disease Control in August 2010; revised August 2011.

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Production of this document has been made possible through a financial contribution from the Public Health Agency of Canada.

ISBN: 978-1-926933-01-6

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