



Health Canada Santé
Canada Canada

GUIDANCE DOCUMENT- Safety and efficacy requirements for hard surface disinfectant drugs

January 2014

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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Table of contents

Introduction..... 1

1.1 Policy objectives 1

1.2 Policy statements 1

1.3 Scope and application 2

Guidance for implementation 2

2.1 Efficacy requirements 2

2.1.1 Requirements for disinfectants used against bacteria 3

2.1.1.1 Levels of efficacy and test organisms 3

2.1.1.2 Specific claims against additional bacteria 3

2.1.1.3 Batch replication requirements and number of carriers or replicates 3

2.1.1.4 Required microbial counts and performance standards 4

2.1.2 Requirements for disinfectants used against fungi 4

2.1.2.1 Levels of efficacy and test organisms 4

2.1.2.2 Specific claims against fungi 5

2.1.2.4 Required microbial counts and performance standards 5

2.1.3 Requirements for disinfectants used against viruses 5

2.1.3.1 Levels of efficacy and test organisms 6

2.1.3.2 Claims against viruses supported by surrogate efficacy 6

2.1.3.3 Batch replication requirements and number of carriers or replicates 6

2.1.3.4 Required microbial counts and performance standards 7

2.1.4 Requirements for disinfectants used against mycobacteria 7

2.1.4.1 Levels of efficacy and test organisms 7

2.1.4.2 Specific claims against mycobacteria 8

2.1.4.3 Batch replication requirements and number of carriers or replicates 8

2.1.4.4 Required microbial counts and performance standards 8

2.1.5 Requirements for disinfectants used against bacterial spores 9

2.1.5.1 Levels of efficacy and test organisms 9

2.1.5.2 Specific claims against bacterial spores 9

2.1.5.3 Considerations for testing against vegetative cells 9

2.1.5.4 Batch replication requirements and number of carriers or replicates 9

2.1.6 Requirements for non-food contact surface sanitizer claims 10

2.1.6.1 Levels of efficacy and test organisms 11

2.1.6.2 Specific claims against additional bacteria 11

2.1.6.3	Batch replication requirements and number of carriers or replicates	11
2.1.6.4	Required microbial counts and performance standards	11
2.1.7	Requirements for food contact surface sanitizer claims.....	11
2.1.7.1	Levels of efficacy and test organisms	12
2.1.7.2	Specific claims against additional bacteria	12
2.1.7.3	Batch replication requirements and number of carriers or replicates	12
2.1.7.4	Required microbial counts and performance standards	13
2.2	Safety requirements.....	13
2.2.1	Remaining residues and surface compatibility concerns	13
	Effective date	14
	Appendices.....	15
	Appendix 1: References	15
	Appendix 2: Efficacy testing criteria for bacteria.....	18
	Appendix 3: Efficacy testing criteria for fungi	19
	Appendix 4: Efficacy testing criteria for viruses	20
	Appendix 5: Efficacy testing criteria for viruses supported by surrogates	21
	Appendix 6: Efficacy testing criteria for mycobacteria	22
	Appendix 7: Efficacy testing criteria for bacterial spores	23
	Appendix 8: Efficacy testing criteria for non-food contact surface sanitizers.....	24
	Appendix 9: Efficacy testing criteria for food contact surface sanitizers	25
	Appendix 10: Labelling considerations for hard surface disinfectants.....	26
1.0	Intended use areas and surfaces	26
1.1	Food processing and preparation areas	26
1.2	Animal housing areas.....	27
1.3	Surfaces/objects in contact with children at the mouthing stage of development	27
1.4	Restrictive statement for disinfectants for use on non-critical medical devices	28
2.0	Pre-cleaning instructions.....	28
3.0	Claims against bloodborne viral pathogens	28
4.0	Claims against spores of <i>clostridium difficile</i>	29
5.0	Claims against emerging viral pathogens	29

Introduction

This guidance document outlines the information considered necessary to support the safety and efficacy of chemical products that meet the regulatory definition of an “antimicrobial agent” (i.e., disinfectants represented for use on non-critical medical devices, environmental surfaces and inanimate objects), which are regulated as drugs under the *Food and Drugs Act* and *Regulations*. These products are commonly referred to as “hard surface disinfectants”, and their label claims may represent the product as being effective against bacteria, fungi, viruses, mycobacteria, or bacterial spores. Additionally, these products may indicate hard non-porous food contact and non-food contact surface sanitizer claims on their label, in which case they are referred to as “disinfectant-sanitizers”.

An overview of the regulation of disinfectant drugs in Canada, an outline of the general information considered necessary to support their safety, efficacy and quality, and the labelling requirements for these products are addressed in a separate guidance document:

- Disinfectant drugs (2014)

The safety and efficacy requirements specific to high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices, and for contact lens disinfectants are addressed in separate guidance documents:

- Safety and efficacy requirements for high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices (2014)
- Safety and efficacy requirements for contact lens disinfectants (2014)

An overview of the application streams applicable to disinfectant drugs is available in the following guidance document:

- Management of disinfectant drug applications (2014)

1.1 Policy objectives

The objective of this guidance document is to provide applicants of hard surface disinfectants and disinfectant-sanitizers the necessary information to comply with the *Food and Drugs Act* and *Regulations*.

1.2 Policy statements

Applicants must provide Health Canada with sufficient information to support the safety, efficacy and quality of a disinfectant drug when used in accordance with the label’s recommended conditions of use before market authorization can be granted.

Health Canada must evaluate this information and determine whether a drug identification number (DIN) should be issued.

1.3 Scope and application

This guidance document applies to products regulated as drugs under the *Food and Drugs Act* and *Regulations* 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, referred to as “hard surface disinfectants”, and that additionally may indicate hard non-porous food and non-food contact surface sanitizer claims on their labelling, in which case they are referred to as “disinfectant-sanitizers”.

All hard surface disinfectants and disinfectant-sanitizers must also meet the general safety, efficacy and quality requirements outlined in the guidance document entitled *Disinfectant Drugs* (2014), except as noted, as well as the labelling requirements set out by the *Food and Drugs Act* and *Regulations*.

Guidance for implementation

2.1 Efficacy requirements

The information in the following sections provides applicants with the efficacy data requirements considered necessary to support a hard surface disinfectant or disinfectant-sanitizer. These requirements are in addition to the general efficacy data considerations (e.g., efficacy data reporting, Good Laboratory Practices, organic burden, contact time) specified in Section 2.1 of the *Disinfectant Drugs* guidance document.

The efficacy test methods in this guidance document are not exhaustive and other appropriately validated test methods and protocols may be acceptable (e.g., those published by standards organizations or recommended by other international regulators). Applicants are encouraged to contact Health Canada in advance of submitting an application to verify whether alternate test methods will be accepted.

Applicants are reminded that efficacy testing should be conducted using the current official version of all test methods, and applicants should note that:

- The microbial counts (i.e., inoculum counts or carrier counts) prescribed in the test methods must be met for the testing to be valid. For test methods which do not prescribe this information, the microbial counts specified in the following sections must be met.
- The performance criteria prescribed in the test methods must be met to support efficacy claims. For test methods which do not prescribe this information, the performance criteria specified in the following sections must be met.

- When microbial counts exceed the prescribed levels and the product meets the prescribed performance criteria, the testing will be considered acceptable, unless otherwise specified in the test methods.

2.1.1 Requirements for disinfectants used against bacteria

This section addresses efficacy testing requirements for label claims against vegetative bacteria when the test methods recommended in Appendix 2 are used.

2.1.1.1 Levels of efficacy and test organisms

The label claims “bactericide” and “bactericidal” require data to support any of the following levels of efficacy:

- a) **Limited disinfectant:** Efficacy data is required against *Salmonella enterica* (ATCC 10708) (Gram-negative) or *Staphylococcus aureus* (ATCC 6538) (Gram-positive).
- b) **General disinfectant:** Efficacy data is required against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538).
- c) **Hospital disinfectant:** Efficacy data is required against *Pseudomonas aeruginosa* (ATCC 15442) and *Staphylococcus aureus* (ATCC 6538).

Disinfectants represented for use in both general and hospital settings require efficacy data against all three of the specified bacteria (i.e., *S. enterica*, *S. aureus* and *P. aeruginosa*).

Disinfectants with efficacy as a general disinfectant or a hospital disinfectant can be registered with the label claims “germicide” or “kills germs”.

Note that *Salmonella enterica* (ATCC 10708) was formerly designated as *Salmonella choleraesuis* (ATCC 10708). Applicants are encouraged to use the current nomenclature for this bacterium in their product labelling.

2.1.1.2 Specific claims against additional bacteria

Once the efficacy for a product has been demonstrated for the general disinfectant claim or the hospital disinfectant claim, efficacy data may be submitted to support additional bacteria claimed on the label (e.g., *Escherichia coli*).

2.1.1.3 Batch replication requirements and number of carriers or replicates

- a) **For limited, general or hospital disinfectant claims:** Testing against 3 samples of the product, representing 3 separately compounded batches, per bacterium is required.

- All 3 batches should be formulated at or below the lower active ingredient limit or the lower certified limit. Once this requirement is met, all additional bacteria claims do not need to be tested at the lower limit.
 - Testing of 60 inoculated carriers per batch per bacterium is required.
- b) **For specific claims against additional bacteria:** Testing against 2 samples of the product, representing 2 separately compounded batches per bacterium is acceptable.
- Testing of 10 inoculated carriers per batch per bacterium is acceptable.

2.1.1.4 Required microbial counts and performance standards

- a) **For limited, general or hospital disinfectant claims**
- 59 of the 60 carriers tested must be negative for growth per batch per bacterium at the proposed contact time to support the efficacy claim, unless otherwise prescribed in the test method. For example, when the AOAC 955.15 and AOAC 964.02 methods are used to support efficacy claims against *S. aureus* and *P. aeruginosa*, the performance criteria prescribed in the current official version of the test methods must be met.
- b) **For claims against additional bacteria**
- A minimum mean of 1×10^4 colony forming units (CFU) per carrier ($4 \log_{10}$ density) is required for a valid test, unless otherwise prescribed in the test method.
 - Once efficacy for a product has been demonstrated for the general disinfectant claim or the hospital disinfectant claim, 10 of the 10 carriers tested must be negative for growth per batch per additional bacterium at the proposed contact time to support the efficacy claim, unless otherwise prescribed in the test method.

2.1.2 Requirements for disinfectants used against fungi

This section addresses efficacy testing requirements for label claims against pathogenic fungi when the test methods recommended in Appendix 3 are used.

To make label claims against fungi, note that efficacy for the general disinfectant claim or the hospital disinfectant claim must also be demonstrated.

2.1.2.1 Levels of efficacy and test organisms

The label claims “fungicide” and “fungicidal” require efficacy data against *Trichophyton mentagrophytes* (ATCC 9533).

2.1.2.2 Specific claims against fungi

Efficacy data may be submitted to support any specific pathogenic fungus claimed on the label (e.g., *Aspergillus brasiliensis*). However, in the absence of efficacy data to support the “fungicide” claim for a product, only specific claims attesting to the efficacy of the product against specific fungi should be indicated on the product label (i.e., “effective against *Aspergillus brasiliensis*” or “kills *Aspergillus brasiliensis*”).

2.1.2.3 Batch replication requirements and number of carriers or replicates

For all fungal claims

- Testing against 2 samples of the product, representing 2 separately compounded batches per fungus is required.
- Both batches tested in support of a “fungicide” claim should be formulated at or below the lower active ingredient limit or the lower certified limit. Once this requirement is met, all additional fungal claims do not need to be tested at the lower limit.
- In the absence of efficacy data to support the “fungicide” claim, both batches submitted in support of all specific fungal claims should be formulated at or below the lower limit.
- For the carrier test methods, testing of 10 inoculated carriers per batch per fungus is required.

2.1.2.4 Required microbial counts and performance standards

For all fungal claims

- A geometric mean of 1×10^4 – 1×10^5 conidia per carrier ($4 - 5 \log_{10}$ average density) is required for a valid test, unless otherwise prescribed in the test method.
- For the AOAC 955.17 method, the test should be conducted at 5, 10 and 15 minute exposure times. All fungal spores should be killed at 10 and 15 minutes to support a 10 minute contact time.
- For the carrier test methods, 10 of the 10 carriers tested must be negative for growth per batch per fungus at the proposed contact time to support the efficacy claim, unless otherwise prescribed in the test method.

2.1.3 Requirements for disinfectants used against viruses

This section addresses efficacy testing requirements for label claims against viruses when the test methods recommended in Appendix 4 and 5 are used.

To make label claims against viruses, note that efficacy for the general disinfectant claim or the hospital disinfectant claim must also be demonstrated.

2.1.3.1 Levels of efficacy and test organisms

Products claiming efficacy against viruses on their label require data to support either of the following levels of efficacy:

- a) **Virucide:** A disinfectant represented as having efficacy against any specific virus (i.e., the product has demonstrated “virucidal” efficacy).
 - Efficacy data may be submitted to support any specific virus (e.g., Influenza A virus).
- b) **Broad-spectrum virucide:** A disinfectant represented as having efficacy against a representative hard to kill non-enveloped virus, and which is expected to inactivate other non-enveloped and enveloped viruses (i.e., the product has demonstrated “broad-spectrum virucidal” efficacy).
 - Efficacy data is considered necessary against Poliovirus type 1, Chat strain (ATCC VR-1562) **or** Human adenovirus type 5 (ATCC VR-5 or VR-16) **or** Bovine parvovirus (ATCC VR-767) **or** Canine parvovirus (ATCC VR-2017).

2.1.3.2 Claims against viruses supported by surrogate efficacy

Health Canada allows label claims against the following viruses to be supported using surrogate viruses for efficacy testing:

- a) **Hepatitis B virus (HBV):** Efficacy data conducted using the duck hepatitis B virus (DHBV) is considered acceptable as a surrogate to support an efficacy claim against the human hepatitis B virus.
- b) **Hepatitis C virus (HCV):** Efficacy data conducted using the bovine viral diarrhea virus (BVDV) is considered acceptable as a surrogate to support an efficacy claim against the human hepatitis C virus.
- c) **Norovirus:** Efficacy data conducted using the feline calicivirus is considered acceptable as a surrogate to support an efficacy claim against the Norwalk virus or Norwalk-like viruses (i.e., Human Noroviruses).

2.1.3.3 Batch replication requirements and number of carriers or replicates

- a) **For virucide claims:** Testing against 2 samples of the product, representing 2 separately compounded batches per virus is required.
 - Both batches should be formulated at or below the lower active ingredient limit or the lower certified limit. Once this requirement is met for the hardest to kill virus on the product label (e.g., a small-sized non-enveloped virus, if applicable), additional virus claims do not need to be tested at the lower limit. Only one virus claim must be tested at or below the lower limit.

- Testing of 1 inoculated carrier per batch per virus is acceptable, with the exception of virus claims supported by surrogate efficacy (i.e., Hepatitis B virus, Hepatitis C virus, and Norovirus).
- b) **For broad-spectrum virucide claim:** Testing against 3 samples of the product, representing 3 separately compounded batches, using one of the virus strains identified in section 2.1.3.1 (b) is required.
- All 3 batches should be formulated at or below the lower active ingredient limit or the lower certified limit.
 - Testing of 5 inoculated carriers per batch per virus is required.
- c) **For virus claims supported by surrogate efficacy (as specified in section 2.1.3.2):** Testing against 2 samples of the product, representing 2 separately compounded batches per virus is required.
- Both batches should be formulated at or below the lower active ingredient limit or the lower certified limit unless this requirement has been met for claims against any harder to kill viruses indicated on the product label (e.g., small-sized non-enveloped viruses).
 - Testing of 2 inoculated carriers per batch per virus is required.

2.1.3.4 Required microbial counts and performance standards

For all virus claims: Unless otherwise prescribed in the current version of the recommended test methods, the following requirements must be met:

- A minimum recoverable endpoint viral titer after drying of 4 log₁₀ is required.
- Complete inactivation of the virus must be demonstrated at all dilutions at the proposed contact time to support the efficacy claim.
- If cytotoxicity is present, a minimum 3 log₁₀ reduction in viral titer beyond the cytotoxic level for all test carriers is required.

2.1.4 Requirements for disinfectants used against mycobacteria

This section addresses efficacy testing requirements for label claims against mycobacteria when the test methods recommended in Appendix 6 are used.

To make label claims against mycobacteria, note that efficacy for the general disinfectant claim or the hospital disinfectant claim must also be demonstrated.

2.1.4.1 Levels of efficacy and test organisms

The label claims “mycobactericide”, “mycobactericidal”, “tuberculocide” and “tuberculocidal” require efficacy data against a representative *Mycobacterium* species (e.g., *M. bovis* BCG, *M. terrae*). Note that *M. terrae* (ATCC 15755) has only been validated with the ASTM quantitative carrier methods (ASTM E2111 and E2197), as well as the OECD quantitative method.

2.1.4.2 Specific claims against mycobacteria

Efficacy data may be submitted to support any specific mycobacteria claimed on the label (e.g., *Mycobacterium fortuitum*). However, in the absence of efficacy data to support the “mycobactericide”, “mycobactericidal”, “tuberculocide” or “tuberculocidal” claims for a product, only specific claims attesting to the efficacy of the product against specific mycobacteria should be indicated on the product label (i.e., “effective against *Mycobacterium fortuitum*” or “kills *Mycobacterium fortuitum*”).

2.1.4.3 Batch replication requirements and number of carriers or Replicates

For all mycobacteria claims

- Testing against 2 samples of the product, representing 2 separately compounded batches per mycobacteria is required.
- Both batches tested in support of a “mycobactericide” claim should be formulated at or below the lower active ingredient limit or the lower certified limit. Once this requirement is met, all additional mycobacteria claims do not need to be tested at the lower limit.
- In the absence of efficacy data to support the “mycobactericide” claim, both batches submitted in support of all specific claims against mycobacteria should be formulated at or below the lower limit.
- Testing of 10 inoculated carriers per batch per mycobacteria is required, except when testing is conducted using the U.S. EPA Quantitative Tuberculocidal Test Method (QTB), which requires 4 replicates per batch.

2.1.4.4 Required microbial counts and performance standards

For all mycobacteria claims

- A minimum geometric mean of 1×10^4 colony forming units (CFU) per carrier is required for a valid qualitative test, unless otherwise prescribed in the test method.
- For the qualitative test method, 10 of the 10 carriers tested must be negative for growth per batch per mycobacteria at the proposed contact time, with no growth in any of the inoculated subculture media, to support the efficacy claim, unless otherwise prescribed in the test method.
- For the U.S. EPA Quantitative Tuberculocidal Test Method (QTB), a minimum 99.99% reduction is required.

2.1.5 Requirements for disinfectants used against bacterial spores

This section addresses efficacy testing requirements for label claims against bacterial spores when the test methods recommended in Appendix 7 are used.

2.1.5.1 Levels of efficacy and test organisms

The label claims “sporicide” and “sporicidal” require efficacy data against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584).

2.1.5.2 Specific claims against bacterial spores

Once efficacy for a product has been demonstrated for the hospital disinfectant claim, efficacy data may be submitted to support other specific bacterial spores claimed on the label (e.g., *Clostridium difficile*). However, in the absence of efficacy data to support the “sporicide” or “sporicidal” claims for a product, only specific claims attesting to the efficacy of the product against specific bacterial spores should be indicated on the product label (i.e., “inactivates spores of *Clostridium difficile*” or “kills spores of *Clostridium difficile*”).

2.1.5.3 Considerations for testing against vegetative cells

For claims against *C. difficile*, *B. subtilis*, and *C. sporogenes*, applicants should ensure that efficacy testing is conducted using the viable spore form as Health Canada does not consider testing using the vegetative cells of these bacteria to be appropriate.

Applicants seeking to test other spore forming bacteria are encouraged to contact Health Canada in advance of submitting an application in order to determine what data requirements may be considered acceptable to support the claims.

2.1.5.4 Batch replication requirements and number of carriers or replicates

- a) **For sporicide claim:** Testing against 3 samples of the product, representing 3 separately compounded batches per bacterial spore is required.
- All 3 batches should be formulated at or below the lower active ingredient limit or the lower certified limit.
 - Testing of 60 inoculated carriers for each of 2 different types of carriers, as prescribed in the current version of the AOAC 966.04 method (Method I & II), per batch per bacterial spore is recommended (i.e., 2 carrier types x 2 test microorganisms x 60 carriers/type = 240 carriers per batch sample; 3 product batches x 240 carriers/batch = a total of 720 carriers must be tested).
 - Alternatively, testing of 120 inoculated hard non-porous carriers (e.g., porcelain penicylinders or glass slides) per batch per bacterial spore is acceptable (i.e., 1 carrier

type x 2 test microorganisms x 120 carriers/type = 240 carriers per batch sample; 3 product batches x 240 carriers/batch = a total of 720 carriers must be tested).

- b) **For *Clostridium difficile* claim:** When testing using a recommended quantitative carrier method (e.g., AOAC 2008.05 or ASTM E2197), testing against 3 samples of the product, representing 3 separately compounded batches, is required.
- All 3 batches should be formulated at or below the lower active ingredient limit or the lower certified limit.
 - Testing of 10 inoculated hard non-porous carriers (e.g., glass slides for AOAC 2008.05; stainless steel disks for ASTM E2197) per batch is acceptable.

2.1.5.5 Required microbial counts and performance standards

- a) **For sporicide claims**
- The titer of the spore suspension must be sufficiently high to achieve a mean of 1×10^5 – 1×10^6 spores per carrier for the test to be valid, unless otherwise prescribed in the test method.
 - 720 of the 720 carriers tested must be negative for growth at the proposed contact time to support the efficacy claim, unless otherwise prescribed in the test method.
- b) **For *Clostridium difficile* claim without sporicide claim:** When testing using a recommended quantitative carrier method (e.g., AOAC 2008.05 or ASTM E2197):
- For the ASTM E2197 method: The titer of the spore suspension must be sufficiently high to achieve a minimum mean of 1×10^6 spores per carrier for the test to be valid, unless otherwise prescribed in the test method.
 - For the AOAC 2008.05 method: The titer of the spore suspension must be sufficiently high to achieve a mean of 5×10^6 – 5×10^7 spores per carrier for the test to be valid, unless otherwise prescribed in the test method.
 - For both test methods: The product must achieve a mean $6 \log_{10}$ reduction based on recoverable spores within the proposed contact time for all carriers, unless otherwise prescribed in the test method.
 - For testing single-use towelettes (on the basis of the expressed liquid): In addition to the efficacy testing, a determination of the amount of time the carrier remains wet should be made. This wetness determination is used to generate the contact time to be used in the efficacy test.

2.1.6 Requirements for non-food contact surface sanitizer claims

This section addresses efficacy testing requirements for non-food contact surface sanitizer label claims against vegetative bacteria indicated on disinfectant drug labelling (i.e., a disinfectant-sanitizer), when the test methods recommended in Appendix 8 are used.

Applicants seeking to market disinfectants with residual self-sanitizing claims are encouraged to contact Health Canada in order to determine what data requirements may be considered acceptable to support the claims.

2.1.6.1 Levels of efficacy and test organisms

The label claim “non-food contact surface sanitizer” requires efficacy data against *Staphylococcus aureus* (ATCC 6538) **and** *Klebsiella pneumoniae* (ATCC 4352), **or** *Enterobacter aerogenes* (ATCC 13048) may be substituted for *K. pneumoniae*.

2.1.6.2 Specific claims against additional bacteria

Once the sanitizer efficacy for a product has been demonstrated against the required representative bacteria, efficacy data may be submitted to support any additional specific bacteria claimed on the label (e.g., *Escherichia coli*).

2.1.6.3 Batch replication requirements and number of carriers or replicates

- a) **For the non-food contact surface sanitizer claim:** Testing against 3 samples of the product, representing 3 separately compounded batches per bacterium is required.
- All 3 batches tested in support of a “non-food contact surface sanitizer” claim should be formulated at or below the lower active ingredient limit or the lower certified limit. Once this requirement is met, all additional non-food contact surface sanitizer claims do not need to be tested at the lower limit.
 - Testing of 5 inoculated carriers per batch per bacterium is required.
- b) **For specific claims against additional bacteria:** Once efficacy for a product has been demonstrated for the sanitizer claim, testing against 2 samples of the product, representing 2 separately compounded batches per bacterium is acceptable.
- Testing of 5 inoculated carriers per batch per bacterium is required.

2.1.6.4 Required microbial counts and performance standards

For all non-food contact surface sanitizer claims

- A 99.9% mean reduction (3 log₁₀ minimum) for each bacterium must be demonstrated within a 5 minute contact time, unless otherwise prescribed in the test method.

2.1.7 Requirements for food contact surface sanitizer claims

This section addresses efficacy testing requirements for food contact surface sanitizer label claims against vegetative bacteria indicated on disinfectant drug labelling (i.e., a disinfectant-sanitizer), when the test methods recommended in Appendix 9 are used.

2.1.7.1 Levels of efficacy and test organisms

The label claim “food contact surface sanitizer” requires data against certain bacteria depending on the chemical nature of the product.

- a) **For non-halide products:** Includes sanitizers that are formulated with quaternary ammonium compounds, chlorinated trisodium phosphate and anionic detergent-acid formulations.
 - Efficacy data is required against *Escherichia coli* (ATCC 11229) **and** *Staphylococcus aureus* (ATCC 6538).
- b) **For halide products:** Includes sanitizers that are formulated with iodophors, mixed halides, and chlorine-bearing chemicals.
 - Efficacy data is required against *Salmonella enterica serovar Typhi* (ATCC 6539) **or** *Staphylococcus aureus* (ATCC 6538).
- c) **For towelette products:** Includes sanitizers manufactured as single-use pre-saturated towelettes formulated with any chemical composition.
 - Efficacy data is required against *Escherichia coli* (ATCC 11229) **and** *Staphylococcus aureus* (ATCC 6538).

Note that *Salmonella enterica serovar Typhi* (ATCC 6539) was formerly designated as *Salmonella typhi* (ATCC 6539). Applicants are encouraged to use the current nomenclature for this bacterium in their product labelling.

2.1.7.2 Specific claims against additional bacteria

Once the sanitizer efficacy for a product has been demonstrated against the required representative bacteria, efficacy data may be submitted to support any additional specific bacteria claimed on the label.

2.1.7.3 Batch replication requirements and number of carriers or replicates

- a) **For the food contact surface sanitizer claim:** Testing against 3 samples of the product, representing 3 separately compounded batches per bacterium is required.
 - All 3 batches tested in support of a “food contact surface sanitizer” claim should be formulated at or below the lower active ingredient limit or the lower certified limit. Once this requirement is met, all additional food contact surface sanitizer claims do not need to be tested at the lower limit.

- The number of carriers or replicates prescribed in the most recent version of the test method must be used for a valid test.
- b) **For specific claims against additional bacteria:** Once efficacy for a product has been demonstrated for the sanitizer claim, testing against 2 samples of the product, representing 2 separately compounded batches per bacterium is acceptable.
- The number of carriers or replicates prescribed in the current version of the test method must be used for a valid test.

2.1.7.4 Required microbial counts and performance standards

a) **For non-halide products**

- A 5 log₁₀ reduction for each bacterium must be demonstrated within a 30 second contact time, unless otherwise prescribed in the test method.

b) **For halide products**

- Test results should demonstrate product concentrations equivalent in activity to 50, 100, or 200 parts-per-million (ppm) of available chlorine (when the reference standard is sodium hypochlorite), unless otherwise prescribed in the test method.

c) **For towelette products**

- A minimum 99.999% reduction for each bacterium must be demonstrated within a 30 second contact time, unless otherwise prescribed in the test method.

2.2 Safety requirements

The information in the following sections provides applicants with the safety data requirements considered necessary to support a hard surface disinfectant or disinfectant-sanitizer. These requirements are in addition to the general safety data considerations specified in Section 2.2 of the Disinfectant Drugs guidance document.

2.2.1 Remaining residues and surface compatibility concerns

The presence and significance of potential residues remaining on a disinfected surface or object and the potential for incompatibility between a proposed disinfectant and a target surface represent important safety concerns to consider for all hard surface disinfectants. In order to mitigate these concerns, applicants should ensure that their labelling addresses the following information, with recommended statements and potential alternatives to labelling specified in Appendix 10:

- Appropriate rinse statements following the use of the disinfectant, where appropriate (e.g., for surfaces or objects that may come into direct contact with food or beverages, with animal feed or drinking water, or with children at the mouthing stage of development); and

- Appropriate restrictive use statements for known significant surface compatibility concerns associated with the use of disinfectant (e.g., the potential for sodium hypochlorite to damage to aluminum surfaces).

Effective date

This guidance document will come into effect 90 days following the date of publication. All disinfectant drug submissions received after the effective date are expected to be filed with the updated supporting data requirements. Data reports which have been signed off as completed prior to the effective date of this guidance document will be assessed at Health Canada's discretion for their acceptability under the updated data requirements.

Appendices

Appendix 1: References

Ascenzi JM, Ezzell RJ, Wendt TM. (1987) *A More Accurate Method for Measurement of Tuberculocidal Activity of Disinfectants*. Applied and Environmental Microbiology, 53(9): 2189-2192.

AOAC: 2008.05 *Quantitative Three Step Method*. In Official Methods of Analysis of AOAC International: Chapter 6 - Disinfectants. USA; Current edition.

AOAC: 955.14 *Use Dilution Method: Testing Disinfectants Against Salmonella choleraesuis*. In: Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 955.15 *Use Dilution Method: Testing Disinfectants against Staphylococcus aureus*. In: Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 955.16 *Chlorine (Available) in Disinfectants: Germicidal Equivalent Concentration*. In Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 955.17 *Fungicidal Activity of Disinfectants*. In Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 960.09 *Germicidal and Detergent Sanitizing Action of Disinfectants*. In Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA, Current edition.

AOAC: 961.02 *Germicidal Spray Products as Disinfectants*. In: Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 964.02 *Use Dilution Method: Testing Disinfectants against Pseudomonas aeruginosa*. In: Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 965.12 *Tuberculocidal Activity of Disinfectants*. In Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

AOAC: 966.04: *Sporicidal Activity of Disinfectants*. In Official Methods of Analysis of AOAC International: Chapter 6 – Disinfectants. USA; Current edition.

ASTM: *E1053 Method: Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces*. In Annual Book of ASTM Standards. USA; Current edition.

ASTM: *E1153 Method: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces*. In Annual Book of ASTM Standards. USA; Current edition.

ASTM: *E2111 Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal and Sporocidal Potencies of Liquid Chemical Germicides*. In Annual Book of ASTM Standards. USA, Current edition.

ASTM: *E2197 Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporocidal Activities of Liquid Chemical Germicides*. In Annual Book of ASTM Standards. USA; Current edition.

ASTM: *E2362 Standard Practice for Evaluation of Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection*. In: Annual Book of ASTM Standards. USA; Current edition.

ASTM: *E2839 Standard Test Method for Production of Clostridium difficile Spores for Use in Efficacy Evaluation of Antimicrobial Agents*. In: Annual Book of ASTM Standards. USA; Current edition.

ASTM: *E2895 Standard Test Method for Production of High Titers of Viable and Semi-Purified Spores of Clostridium difficile using a Liquid Medium*. In: Annual Book of ASTM Standards. USA; Current edition.

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U.S. EPA (2002): United States Environmental Protection Agency. *Virucidal Effectiveness Test Using Bovine Viral Diarrhea Virus (BVDV) As Surrogates for Human Hepatitis C Virus*. Office of Pesticide Programs, Antimicrobials Division. USA; 2002.

U.S. EPA (2001): United States Environmental Protection Agency. *Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes*. Office of Pesticide Programs, Antimicrobials Division. USA; 2001.

U.S. EPA (2009): *Quantitative Suspension Test Method for Determining Tuberculocidal Efficacy of Disinfectants Against Mycobacterium bovis (BCG): Standard Operating Procedure*. Office of Pesticide Programs, Antimicrobials Division. USA; 2009.

Appendix 2: Efficacy testing criteria for bacteria

Table 1: Efficacy Testing Criteria for Bacteria

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count	Performance Criteria for Efficacy
Limited Disinfectant (effective against Gram-positive OR Gram-negative, but not both)	<ul style="list-style-type: none"> Liquids Powders 	AOAC Use-Dilution Method <ul style="list-style-type: none"> 955.14 955.15 	<i>Salmonella enterica</i> (ATCC 10708) OR <i>Staphylococcus aureus</i> (ATCC 6538)	<ul style="list-style-type: none"> 3 batches 60 carriers 	As prescribed in current test methods.	As prescribed in current test methods & at proposed contact time. Unless otherwise prescribed: <ul style="list-style-type: none"> 59/60 carriers negative for growth per batch per bacterium at proposed contact time.
	<ul style="list-style-type: none"> Spray Products 	<ul style="list-style-type: none"> AOAC 961.02 				
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> Modified AOAC 961.02 ASTM E2362 				
General Disinfectant (effective against Gram-positive AND Gram-negative)	<ul style="list-style-type: none"> Liquids Powders 	AOAC Use-Dilution Method <ul style="list-style-type: none"> 955.14 955.15 	<i>Salmonella enterica</i> (ATCC 10708) AND <i>Staphylococcus aureus</i> (ATCC 6538)		As prescribed in current test methods.	Note: When the AOAC 955.15 and AOAC 964.02 methods are used to support efficacy claims against <i>S. aureus</i> and <i>P. aeruginosa</i> , the performance criteria prescribed in the current official version of the test methods must be met.
	<ul style="list-style-type: none"> Spray Products 	<ul style="list-style-type: none"> AOAC 961.02 				
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> Modified AOAC 961.02 ASTM E2362 				
Hospital Disinfectant (effective against Gram-positive AND Gram-negative)	<ul style="list-style-type: none"> Liquids Powders 	AOAC Use-Dilution Method <ul style="list-style-type: none"> 964.02 955.15 	<i>Pseudomonas aeruginosa</i> (ATCC 15442) AND <i>Staphylococcus aureus</i> (ATCC 6538)		As prescribed in current test methods.	Unless otherwise prescribed: <ul style="list-style-type: none"> 10/10 carriers negative for growth per batch at proposed contact time.
	<ul style="list-style-type: none"> Spray Products 	<ul style="list-style-type: none"> AOAC 961.02 				
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> Modified AOAC 961.02 ASTM E2362 				
Claim against additional bacterium	<ul style="list-style-type: none"> Liquids Powders 	AOAC Use-Dilution Method	Any specific bacterium claimed on the label in addition to the general or hospital disinfectant claim.	<ul style="list-style-type: none"> 2 batches 10 carriers 	As prescribed in current test methods. Unless otherwise prescribed: <ul style="list-style-type: none"> A minimum mean of 1×10^4 colony forming units (CFU) per carrier is required (mean $4 \log_{10}$ density). 	Unless otherwise prescribed: <ul style="list-style-type: none"> 10/10 carriers negative for growth per batch at proposed contact time.
	<ul style="list-style-type: none"> Spray Products 	<ul style="list-style-type: none"> AOAC 961.02 				
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> Modified AOAC 961.02 ASTM E2362 				

Appendix 3: Efficacy testing criteria for fungi

Table 2: Efficacy Testing Criteria for Fungi

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count	Performance Criteria for Efficacy
Fungicide	<ul style="list-style-type: none"> Liquids Powders 	<ul style="list-style-type: none"> AOAC 955.17 AOAC Use-Dilution Methods (UDM) Modified for Fungi 	<i>Trichophyton mentagrophytes</i> (ATCC 9533)	<ul style="list-style-type: none"> 2 batches 10 carriers (for the carrier test methods) 	As prescribed in current test methods.	As prescribed in current test methods & at proposed contact time.
	<ul style="list-style-type: none"> Spray Products 	<ul style="list-style-type: none"> AOAC 961.02 				
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> Modified AOAC 961.02 ASTM E2362 				
Claim against specific fungus	<ul style="list-style-type: none"> Liquids Powders 	<ul style="list-style-type: none"> AOAC 955.17 AOAC Use-Dilution Methods (UDM) Modified for Fungi 	Any specific fungus claimed on the label.	<ul style="list-style-type: none"> 2 batches 10 carriers (for the carrier test methods) 	Unless otherwise prescribed: <ul style="list-style-type: none"> The inoculum employed should be modified to provide a geometric mean of $1 \times 10^4 - 1 \times 10^5$ conidia per carrier (4 -5 \log_{10} average density).. 	For AOAC 955.17: <ul style="list-style-type: none"> The test should be conducted at 5, 10 and 15 minute exposure times. All fungal spores should be killed at 10 and 15 minutes to support a 10 minute contact time. For the carrier test methods: <ul style="list-style-type: none"> 10/10 carriers negative for growth per batch at the prescribed contact time.
	<ul style="list-style-type: none"> Spray Products 	<ul style="list-style-type: none"> AOAC 961.02 				
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> Modified AOAC 961.02 ASTM E2362 				

Appendix 4: Efficacy testing criteria for viruses

Table 3: Efficacy Testing Criteria for Viruses

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count	Performance Criteria for Efficacy
Virucide	<ul style="list-style-type: none"> Liquids Powders 	<ul style="list-style-type: none"> ASTM E1053 AOAC Use-Dilution Methods (UDM) Modified for Viruses 	Any specific virus claimed on the label except: <ul style="list-style-type: none"> The surrogate viruses for efficacy claims against <ul style="list-style-type: none"> Human hepatitis B virus (HBV) Human hepatitis C virus (HCV) Noroviruses (e.g., Norwalk or Norwalk-like viruses) 	<ul style="list-style-type: none"> 2 batches 1 carrier 	As prescribed in current test methods. Unless otherwise prescribed: <ul style="list-style-type: none"> A minimum recoverable endpoint viral titer after drying of 4 log₁₀ per carrier is required. 	As prescribed in current test methods & at proposed contact time. Unless otherwise prescribed: <ul style="list-style-type: none"> Complete inactivation of the virus at all dilutions at proposed contact time; and If cytotoxicity is present, a minimum 3 log₁₀ reduction in viral titer beyond the cytotoxic level for all the test carriers is required.
	Spray Products	<ul style="list-style-type: none"> ASTM E1053 AOAC 961.02 Modified for Viruses 				
	Single-Use Towelettes	<ul style="list-style-type: none"> Modified ASTM E1053 Modified AOAC 961.02 				
Broad spectrum virucide	<ul style="list-style-type: none"> Liquids Powders 	<ul style="list-style-type: none"> ASTM E1053 AOAC Use-Dilution Methods (UDM) Modified for Viruses 	Testing against any of the following viruses: <ul style="list-style-type: none"> Poliovirus type 1 ATCC VR-1562 Chat strain Human Adenovirus type 5 <ul style="list-style-type: none"> ATCC VR-5 ATCC VR-1516 Bovine Parvovirus ATCC VR-767 Canine Parvovirus ATCC VR-2017 	<ul style="list-style-type: none"> 3 batches 5 carriers 		
	Spray Products	<ul style="list-style-type: none"> ASTM E1053 AOAC 961.02 Modified for Viruses 				
	Single-Use Towelettes	<ul style="list-style-type: none"> Modified ASTM E1053 Modified AOAC 961.02 				

Appendix 5: Efficacy testing criteria for viruses supported by surrogates

Table 4: Efficacy Testing Criteria for Viruses Supported by Surrogates

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count	Performance Criteria for Efficacy
Human Hepatitis B virus (HBV) claim supported by surrogate efficacy	<ul style="list-style-type: none"> • Liquids • Powders • Spray Products • Single-Use Towelettes 	<ul style="list-style-type: none"> • U.S. EPA <i>Protocol for Testing the Efficacy of Disinfectants Used to Inactivate Duck Hepatitis B Virus and to Support Corresponding Label Claims</i>¹ 	Duck Hepatitis B virus (DHBV)	<ul style="list-style-type: none"> • 2 batches • 2 carriers 	<p>As prescribed in current test methods.</p> <p>Unless otherwise prescribed:</p> <ul style="list-style-type: none"> • A minimum recoverable endpoint viral titer after drying of 4 log₁₀ per carrier is required. 	<p>As prescribed in current test methods & at proposed contact time.</p> <p>Unless otherwise prescribed:</p> <ul style="list-style-type: none"> • Complete inactivation of the virus at all dilutions at proposed contact time; and • If cytotoxicity is present, a minimum 3 log₁₀ reduction in viral titer beyond the cytotoxic level for all the test carriers is required.
Human Hepatitis C virus (HCV) claim supported by surrogate efficacy	<ul style="list-style-type: none"> • Liquids • Powders • Spray Products • Single-Use Towelettes 	<ul style="list-style-type: none"> • U.S. EPA <i>Virucidal Effectiveness Test Using Bovine Viral Diarrhea Virus (BVDV) as Surrogates for Human Hepatitis C Virus</i>² 	Bovine Viral Diarrhea virus (BVDV)			
Human Norovirus claim supported by surrogate efficacy	<ul style="list-style-type: none"> • Liquids • Powders • Spray Products • Single-Use Towelettes 	<ul style="list-style-type: none"> • U.S. EPA <i>Initial Virucidal Effectiveness Test: Using Feline Calicivirus as Surrogate for Norovirus</i>³ 	Feline Calicivirus			
<ol style="list-style-type: none"> 1. The method validation requirements, which previously required testing in two independent laboratories and the use of two dilutions of BTC 835, have been eliminated. 2. The method validation requirements, which previously required testing in two independent test laboratories and the use of two dilutions of BARDAC 2280, have been eliminated. 3. The method validation requirements, which previously required testing in two independent laboratories and the use of two dilutions of sodium hypochlorite, have been eliminated. 						

Appendix 6: Efficacy testing criteria for mycobacteria

Table 5: Efficacy Testing Criteria for Mycobacteria

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count	Performance Criteria for Efficacy
Mycobactericide / Tuberculocide	<ul style="list-style-type: none"> •Liquids •Powders 	<ul style="list-style-type: none"> •AOAC 965.12 •US EPA QTB¹ 	<p>The selection of the appropriate <i>Mycobacterium</i> species depends on the chosen test method:</p> <p><i>Mycobacterium bovis</i> (BCG) OR <i>Mycobacterium terrae</i>² (ATCC 15755)</p>	<ul style="list-style-type: none"> •2 batches •10 carriers <p><i>For QTB:</i></p> <ul style="list-style-type: none"> • 4 replicates per batch 	<p>As prescribed in current test methods.</p> <p>Unless otherwise prescribed for the qualitative methods:</p> <ul style="list-style-type: none"> • A minimum geometric mean of 1×10^4 CFU per carrier is required. 	<p>As prescribed in current test methods & at proposed contact time.</p> <p>Unless otherwise prescribed for qualitative methods:</p> <ul style="list-style-type: none"> • 10/10 carriers negative for growth per batch at the specified contact time; and • No growth in any of the inoculated subculture media. <p><i>For QTB:</i></p> <ul style="list-style-type: none"> • A minimum 99.99% reduction is required.
	•Spray Products	•Modified AOAC 961.02				
	•Single-Use Towelettes	<ul style="list-style-type: none"> •Modified AOAC 961.02 •ASTM E2362 				
Claim against specific mycobacteria	<ul style="list-style-type: none"> •Liquids •Powders 	<ul style="list-style-type: none"> •AOAC 965.12 •US EPA QTB¹ 	Any specific mycobacteria claimed on the label.			
	•Spray Products	•Modified AOAC 961.02				
	•Single-Use Towelettes	<ul style="list-style-type: none"> •Modified AOAC 961.02 •ASTM E2362 				
<ol style="list-style-type: none"> 1. The US EPA Quantitative Tuberculocidal Test Method (QTB) is only recommended for glutaraldehyde-based products, which have not been validated in the AOAC 965.12 method. This method is based on the research of Ascenzi <i>et al.</i> 2. Unless otherwise prescribed in the most recent version of one of the recommended test methods above, efficacy testing using <i>Mycobacterium terrae</i> (ATCC 15755) has only been validated with the ASTM quantitative carrier tests (ASTM E2111 and ASTM E2197) as well as the OECD quantitative test method. Applicants may choose to alternatively conduct efficacy testing against mycobacteria using these test methods, with a target performance criteria of a mean $4 \log_{10}$ reduction in the viability of the test organism. 						

Appendix 7: Efficacy testing criteria for bacterial spores

Table 6: Efficacy Testing Criteria for Bacterial Spores

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count	Performance Criteria for Efficacy
Sporicide	<ul style="list-style-type: none"> Liquids Powders Single-Use Towelettes Vapour or Gas product for use in a specific device to reprocess non-critical medical devices 	<ul style="list-style-type: none"> AOAC 966.04 <p><i>For towelettes:</i> Use the expressed liquid.</p> <p><i>For vapour or gas products:</i> Expose carriers to test product in the intended specific device according to the directions for use of the device.</p>	<p><i>Bacillus subtilis</i> (ATCC 19659) (use Method II of AOAC 966.04)</p> <p>AND</p> <p><i>Clostridium sporogenes</i> (ATCC 3584) (use Method I of AOAC 966.04)</p>	<ul style="list-style-type: none"> 3 batches 2 types of carriers (suture loop and porcelain penicylinder, as prescribed in current version of test method) 60 carriers per type per batch 	<p>Unless otherwise prescribed:</p> <ul style="list-style-type: none"> Titer of spore suspension high enough to achieve mean of 1×10^5 - 1×10^6 spores per carrier. 	<p>Unless otherwise prescribed:</p> <ul style="list-style-type: none"> 720/720 carriers negative for growth at proposed contact time.
Claim against <i>Clostridium difficile</i>	<ul style="list-style-type: none"> Liquids Powders Single-Use Towelettes 	<ul style="list-style-type: none"> AOAC 2008.05 ASTM E2197 <p><i>For towelettes:</i> Use the expressed liquid.</p>	<p><i>Clostridium difficile</i></p> <ul style="list-style-type: none"> ATCC 43598 <p><i>For guidance on production of spore suspension and quality assurance testing (e.g., spore purity and titer, hydrochloric acid resistance):</i></p> <ul style="list-style-type: none"> ASTM E2839 ASTM E2895 	<ul style="list-style-type: none"> 3 batches 1 type of hard non-porous carrier 10 carriers 	<p><i>For ASTM E2197,</i> unless otherwise prescribed:</p> <ul style="list-style-type: none"> Titer of spore suspension high enough to achieve minimum mean of 1×10^6 spores per carrier. <p><i>For AOAC 2008.05,</i> unless otherwise prescribed:</p> <ul style="list-style-type: none"> Titer of spore suspension high enough to achieve mean of 5×10^6 - 5×10^7 spores per carrier. 	<p>Unless otherwise prescribed:</p> <ul style="list-style-type: none"> Mean 6 \log_{10} reduction based on recoverable spores within contact time measured in wetness determination test

Appendix 8: Efficacy testing criteria for non-food contact surface sanitizers

Table 7: Efficacy Testing Criteria for Non-Food Contact Surface Sanitizers

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count
Non-food contact sanitizer	<ul style="list-style-type: none"> Liquids Powders 	<ul style="list-style-type: none"> ASTM E1153 	<i>Staphylococcus aureus</i> (ATCC 6538) AND <i>Klebsiella pneumoniae</i> (ATCC 4352) OR <i>Enterobacter aerogenes</i> (ATCC 13048)	<ul style="list-style-type: none"> 3 batches 5 carriers 	As prescribed in current test method & at proposed contact time. Unless otherwise prescribed: <ul style="list-style-type: none"> 99.9% mean reduction (minimum 3 log₁₀) for each bacterium within 5 minute contact.
	<ul style="list-style-type: none"> Spray Products Single-Use Towelettes 	<ul style="list-style-type: none"> Modified ASTM E1153 			
Claim against additional bacteria	<ul style="list-style-type: none"> Liquids Powders 	<ul style="list-style-type: none"> ASTM E1153 	Any specific bacteria claimed on the label in addition to the non-food contact surface sanitizer claim.	<ul style="list-style-type: none"> 2 batches 5 carriers 	
	<ul style="list-style-type: none"> Spray Products Single-Use Towelette 	<ul style="list-style-type: none"> Modified ASTM E1153 			

Appendix 9: Efficacy testing criteria for food contact surface sanitizers

Table 8: Efficacy Testing Criteria for Food Contact Surface Sanitizers

Claim	Product Form	Recommended Test Methods	Test Organisms	Number of Batches per Organism & Replicates or Carriers per Batch	Inoculum Count or Carrier Count
Food contact surface sanitizer	<ul style="list-style-type: none"> Liquids Powders Spray Products 	For non-halide products: <ul style="list-style-type: none"> AOAC 960.09 	<i>Escherichia coli</i> (ATCC 11229) AND <i>Staphylococcus aureus</i> (ATCC 6538)	<ul style="list-style-type: none"> 3 batches The number of carriers or replicates prescribed in the current test method must be used. 	As prescribed in current test method & at proposed contact time. Unless otherwise prescribed: <ul style="list-style-type: none"> A 5 log₁₀ reduction of each bacterium within 30 seconds.
	<ul style="list-style-type: none"> Liquids Powders Spray Products 	For halide products: <ul style="list-style-type: none"> AOAC 955.16 	<i>Salmonella enterica serovar Typhi</i> (ATCC 6539) OR <i>Staphylococcus aureus</i> (ATCC 6538)		As prescribed in current test method & at proposed contact time. Unless otherwise prescribed: <ul style="list-style-type: none"> Test results should demonstrate product concentrations equivalent in activity to 50, 100, or 200 ppm of available chlorine as labelled (The reference standard is sodium hypochlorite.)
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> U.S. EPA Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes 	<i>Escherichia coli</i> (ATCC 11229) AND <i>Staphylococcus aureus</i> (ATCC 6538)		As prescribed in current test method & at proposed contact time. Unless otherwise prescribed: <ul style="list-style-type: none"> A minimum 99.999% reduction of each bacterium within 30 seconds.
Claim against additional bacteria	<ul style="list-style-type: none"> Liquids Powders Spray Products 	For non-halide products: <ul style="list-style-type: none"> AOAC 960.09 	Any specific bacteria claimed on the label in addition to the food contact surface sanitizer claim.	<ul style="list-style-type: none"> 2 batches The number of replicates or carriers prescribed in the current test method must be used. 	Unless otherwise prescribed: <ul style="list-style-type: none"> A 5 log₁₀ reduction of each bacterium within 30 seconds.
	<ul style="list-style-type: none"> Liquids Powders Spray Products 	For halide products: <ul style="list-style-type: none"> AOAC 955.16 			Unless otherwise prescribed: <ul style="list-style-type: none"> Test results should demonstrate product concentrations equivalent in activity to 50, 100, or 200 ppm of available chlorine as labelled (The reference standard is sodium hypochlorite.)
	<ul style="list-style-type: none"> Single-Use Towelettes 	<ul style="list-style-type: none"> U.S. EPA Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes 			Unless otherwise prescribed: <ul style="list-style-type: none"> A minimum 99.999% reduction of each bacterium within 30 seconds.

Appendix 10: Labelling considerations for hard surface disinfectants

This appendix is intended to assist applicants in preparing appropriate labelling for hard surface disinfectants; however, these are labelling **recommendations only** and are **not** regulatory requirements. These labelling considerations are intended to address the regulatory requirement for adequate directions for all intended uses of a disinfectant drug to be indicated on its labelling.

The information in this appendix should be considered in addition to the general labelling considerations outlined in the guidance document:

- Disinfectant Drugs (2014)

1.0 Intended use areas and surfaces

The intended premises for disinfection for a product (i.e., the drug use options as selected on the HC/SC 3011 *Drug Submission Application Form*) should be specified on the label; these include domestic, industrial/institutional, hospital, food processing, barn settings, or any combination of these. Applicants should note that the drug use option for “medical instruments” is considered by Health Canada to only be applicable for high-level disinfectants and sterilants represented for use on semi-critical or critical medical devices.

Information regarding any known surface compatibility concerns for a disinfectant should be indicated on the label (e.g., the potential for sodium hypochlorite to cause damage to aluminum surfaces).

1.1 Food processing and preparation areas

Disinfectants represented for use on surfaces or objects which may come into direct contact with food or beverages (e.g., counters, eating and drinking utensils, and food processing equipment) should indicate a statement to the effect of the following on their label:

- Avoid contamination of food during application and storage; or
- Do not contaminate food during the use and storage of the product; or
- Avoid contact with food.

In addition, these disinfectants should indicate on their label that at the end of the contact time a rinse with potable water is recommended to remove potential residues from treated surfaces or objects. A statement to the effect of the following is recommended:

- For surfaces and/or objects that may come into direct contact with food, a rinse with potable water is recommended; or
- Rinse surface prior to use.

Alternatively, to support the omission of a rinse statement for a disinfectant intended for use in food processing facilities or for use as a food-contact surface sanitizer (i.e., the product is defined as an incidental additive), applicants are encouraged to contact the Bureau of Chemical Safety

within the Food Directorate to request a voluntary evaluation of the potential hazards associated with the product resulting from incidental contact with food.

1.2 Animal housing areas

Disinfectants represented for use on surfaces or objects in animal housing areas (e.g., floors, walls, cages, and animal equipment), and particularly within industrial/institutional and barn premises (e.g., farms, poultry plants, veterinary clinics, and kennels), should indicate appropriate statements to the effect of the following on their label:

- Remove all animals/poultry and their feed from premises prior to disinfection;
- Remove all heavy soil, such as urine and fecal matter, from surfaces and objects prior to disinfection;
- Empty all feeding and watering appliances prior to disinfection; and
- Following disinfection, do not house animals/poultry until areas have been ventilated.

In addition, disinfectants recommended for use on surfaces or objects that will come into direct contact with animal feed or drinking water (e.g., troughs, automatic feeders, fountains and waterers) should indicate on their label that at the end of the contact time a rinse with potable water is recommended to remove potential residues from the treated surfaces or objects. A statement to the effect of the following is recommended:

- All surfaces and/or objects that will contact feed or drinking water should be rinsed with potable water before reuse.

Alternatively, to support the omission of these statements, applicants are encouraged to contact the Veterinary Drugs Directorate within Health Canada for an evaluation of the product, given that the use of a disinfectant within animal housing areas could pose a safety issue for the animals housed within the premises if the disinfectant itself or any remaining residues from its use were to come into direct contact with or be ingested by them.

1.3 Surfaces/objects in contact with children at the mouthing stage of development

Disinfectants represented for use on surfaces or objects which may come into contact with children at the mouthing stage of development (e.g., toys in daycare centers, schools, hospitals and domestic settings) should indicate on their label that at the end of the contact time a rinse with potable water is recommended to remove potential residues. A statement to the effect of the following is recommended:

- For surfaces and/or objects that may come into direct contact with children at the mouthing stage of development, a rinse with potable water is recommended.

Alternatively, to support the omission of a rinse statement, applicants may choose to submit a scientific rationale and/or safety data to address the presence and significance of potential residues on disinfected surfaces or objects.

1.4 Restrictive statement for disinfectants for use on non-critical medical devices

Disinfectants recommended for use in hospital or healthcare settings on non-critical medical devices only (e.g., stethoscopes, hospital beds, and wheel chairs) should indicate a restrictive statement to the effect of the following on their label:

- This product is not to be used as a sterilant/high-level disinfectant on any surface or instrument that: (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

2.0 Pre-cleaning instructions

Products that are represented for use as a one-step cleaner/disinfectant (i.e., without a pre-cleaning step) should have been tested and found to be effective in the presence of light to moderate amounts of soil (i.e., a 5% organic soil load). Products that are not supported by efficacy testing conducted using an appropriate level of organic soil should specify in their directions for use the need to pre-clean surfaces prior to disinfection or sanitization.

All disinfectants should also specify in their directions for use that heavy amounts of soil present on a target surface should be removed through a pre-cleaning step prior to disinfection or sanitization. A statement to the effect of the following is appropriate:

- For heavily soiled surfaces, a pre-cleaning step is required; or
- Pre-clean heavily soiled areas.

3.0 Claims against bloodborne viral pathogens

Disinfectants labelled with efficacy claims against bloodborne viral pathogens (e.g., Human Immunodeficiency virus, Hepatitis B virus; Hepatitis C virus) should indicate specific directions for use, including:

- a) A statement indicating that the product is intended for use against the bloodborne pathogens in settings where the viruses would be expected to be encountered, such as settings where contamination by blood or body fluid is likely; and
- b) Specific decontamination procedures, to the effect of the following:
 - **Personal protection:** Personnel that clean items soiled with blood or body fluids must wear appropriate personal protective equipment (i.e., barrier protection), such as disposable gloves, gowns, masks or eye coverings;
 - **Cleaning:** Target surfaces must be cleaned prior to disinfection, as the presence of heavy soil on a surface may reduce the intended disinfectant efficacy of the product; and
 - **Infectious materials disposal:** Any materials used in the cleaning process that may contain blood or body fluids are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

4.0 Claims against spores of *Clostridium difficile*

Health Canada does not consider the labelling of a disinfectant with claims against the vegetative cells of spore-forming bacteria to be appropriate, because the vegetative form is not the organism of concern for infection control. Additionally, the claim “*Clostridium difficile* sporicide” is not considered acceptable for products that do not have an established sporicidal claim. Rather, only specific claims attesting to the efficacy of a product against specific bacterial spores should be indicated on the product label (i.e., “inactivates spores of *Clostridium difficile*” or “kills spores of *Clostridium difficile*”).

Disinfectants labelled with efficacy claims against the spore form of *Clostridium difficile* should indicate specific directions for use, including:

- a) A statement indicating that the product is intended for use to kill or inactivate spores of *C. difficile* in settings where it is expected to be encountered, such as settings where contamination by fecal matter is likely; and
- b) Specific decontamination procedures, to the effect of the following:
 - **Personal protection:** Personnel that clean items potentially soiled with spores of *C. difficile* must wear appropriate personal protective equipment (i.e., barrier protection), such as disposable gloves, gowns, masks or eye coverings;
 - **Cleaning procedure:** Target surfaces must be cleaned prior to disinfection, as the presence of heavy soil such as fecal matter on a surface may reduce the intended disinfectant efficacy of the product; and
 - **Infectious materials disposal:** Any materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

5.0 Claims against emerging viral pathogens

When the Public Health Agency of Canada (PHAC) has issued a public notice that an emerging viral pathogen poses a significant risk to Canadians or has been declared by the World Health Organization (WHO) as a public health emergency of international concern, Health Canada will permit manufacturers to provide communications to the public regarding the expected efficacy of certain market authorized disinfectant drugs against the emerging pathogen: this includes communications through their web sites, toll free consumer information services, and similar media.

Disinfectants which have received market authorization for the following claims will be permitted to make efficacy claims against emerging viral pathogens:

- Broad spectrum virucide, supported by an efficacy claim against any of:
 - Adenovirus type 5
 - Bovine Parovirus
 - Canine Parvovirus

- Poliovirus type 1
- For emerging viral pathogens for which the taxonomic genus of the virus has been identified, efficacy data against other viruses within that genus may be considered acceptable (e.g., any Influenza A virus for a claim against Influenza A H1N1).

Manufacturers may add claims against emerging viral pathogens to their market authorized product labels, provided that their products qualify for the claims, through the post-authorization Division 1 change (PDC) process, which requires a notification to be sent to Health Canada within 30 days of adding the claim, as permitted through section C.01.014.4 of the *Food and Drug Regulations*.