Health Canada Santé Canada

HARD SURFACE DISINFECTANTS MONOGRAPH

Date
June 26, 2015

FOREWORD

Health Canada is pleased to announce the finalization of the revised Hard Surface Disinfectants Monograph. This final monograph is intended to replace two previous monographs: Hard Surface Disinfectants (August 2007) and Toilet Bowl Disinfectant Cleaners (August 2007).

This monograph describes the requirements necessary to receive market authorization (i.e., a Drug Identification Number [DIN]) for disinfectants 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). These products, commonly referred to as "hard surface disinfectants," are intended for use as disinfectants on hard, non-porous surfaces. Additionally, these products may indicate non-porous food contact and non-food contact surface sanitizer claims on their label, in which case they are referred to as "disinfectant-sanitizers."

This monograph identifies the permitted active ingredients, minimum in-use concentrations, target microorganism classes, contact times, and associated use areas for these products to be licensed without the submission of additional evidence to Health Canada.

Products which do not meet the criteria outlined in this monograph should apply for market authorization outside of the monograph stream, as indicated in the guidance document entitled *Management of Disinfectant Drug Applications*.

Applicants are not required to submit efficacy data through the monograph process; however, when conducting efficacy testing for their proposed formulations to validate their proposed efficacy claims, applicants should reference the Guidance Document entitled *Disinfectant Drugs* for recommended efficacy test methods and expected performances criteria.

This monograph does not apply to disinfectants with the following indications, which are expected to be supported by appropriate scientific evidence and which require an efficacy assessment as part of their market authorization:

a. disinfectants for use on reusable semi-critical or critical medical devices, including contact lenses;
b. disinfectants with general claims for efficacy against:
    - bacterial spores; as a sporicide, or as a sterilant or high-level disinfectant;
    - mycobacteria; as a mycobactericide, or as an intermediate-level disinfectant;
c. disinfectants with a "broad spectrum virucide" claim;
d. disinfectants with claims for efficacy against specific microorganisms indicated on their labelling;
e. disinfectants with residual self-sanitizing claims (e.g., significant reduction in numbers of infectious microorganisms which may be subsequently deposited on treated hard, non-porous environmental surfaces);
f. disinfectants with anti-biofilms claims;
g. disinfectants intended for use on porous surfaces and inanimate objects (e.g., carpets, fabrics and textiles).

Applicants are reminded that hard surface disinfectants are regulated as drugs, and are subject to the requirements of the *Food and Drug Act* and its *Regulations*. Applicants should consult section 2.4 of the Guidance Document - *Disinfectant Drugs* for information specific to the regulatory labelling requirements for these products.

Applicants should also consult relevant guidance documents, including *Management of Disinfectant Drug Applications*, *Disinfectant Drugs* and *Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs* for additional information.

Note: Additional information may be added to labels, outside of what is specified in this monograph (e.g., non-therapeutic claims), as long as it is consistent with the labelling

recommendations provided within the guidance documents entitled *Disinfectant Drugs* and *Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs*, and is not false, misleading or likely to create an erroneous impression of the product. Applicants are encouraged to consult the Health Product and Food Branch (HPFB) Policy: *Principles for Claims Relating to Comparison of Non-Therapeutic Aspects of Non-prescription Drug Products* for additional information related to the acceptability of non-therapeutic marketing claims on drug products.

Active Ingredient(s)

A list of permitted active ingredients with minimum in-use concentrations, expressed as parts-per-million (ppm), is provided in Table 1. This list is applicable for all hard surface disinfectants, including toilet bowl disinfectants and disinfectant-sanitizers. An additional active ingredient is provided in Table 2 for products intended only for use as toilet bowl disinfectants.

The permitted target microorganism classes, contact times, and associated use areas which are considered acceptable based on the active ingredient(s) and minimum in-use concentrations of a proposed product are also specified in Tables 1 and 2.

All other active ingredients, minimum in-use concentrations, target microorganism classes, contact times, and associated use areas fall outside the scope of this monograph. Products that do not meet the criteria outlined in this monograph should apply for market authorization outside of the monograph stream, as indicated in the guidance document *Management of Disinfectant Drug Applications*.

Combinations of Active Ingredients:

- Combinations of any of the active ingredients from the same category are permitted provided that the total in-use concentration of the combined ingredients meets the minimum stated in Table 1.
- Combinations of any of the active ingredients from the different categories listed in Tables 1 and 2 are permitted provided that the ingredient(s) from one of the categories is present at the minimal in-use concentration for that category, and that the ingredients do not interact in a manner that reduces the disinfectant activity.

Table 1: Permitted Active Ingredients, Minimum In-Use Concentrations, Target Classes of Microorganisms, Contact Times and Use Areas for All Hard Surface Disinfectants, including Toilet Bowl Disinfectants and Disinfectant-Sanitizers

Category	Preferred name	Synonym	Minimum In-Use Concentration	Target Microorganism Classes	Contact Time for Disinfection and Sanitization	Use Areas[1]
Quaternary ammonium compound	Alkyl dimethyl ethyl benzyl ammonium chloride		≥450 ppm	• BACTERIA • VIRUS • FUNGI	10 minutes	• Domestic • Commercial
	Aralkonium chloride	Alkyl dimethyl-3, 4-dichlorobenzyl ammonium chloride				
	Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride				
	Cetalkonium chloride	Cetyl dimethyl benzyl ammonium chloride				
	Didecyl dimethyl ammonium chloride	Chloride didecyl dimethylammonium				
	Dioctyl dimethyl	Chloride dioctyl dimethylammonium				

[1] As per the guidance document entitled *Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs*, the intended premises for disinfection of a product (i.e., the drug use area options as selected on the HC/SC 3011 Drug Submission Application Form) should be specified on the label. For this monograph, these include domestic and commercial (i.e., industrial/institutional, hospital, food processing, barn) use areas.

	ammonium chloride					
	Hexadecyl dimethyl benzyl ammonium chloride	Chloride hexadecyldimethylbenzyl ammonium				
	Methyl dodecyl benzyl trimethyl ammonium chloride	Chloride methyl dodecyl benzyl trimethyl ammonium				
	Octa decyl dimethyl benzyl ammonium chloride	Chloride octadecyl dimethylbenzyl ammonium				
	Octyl decyl dimethyl ammonium chloride	Chloride octyl decyl dimethyl ammonium				
	Octyl dimethyl ammonium chloride	Chloride octyl dimethyl ammonium				
Phenolic	Chloro-ortho-phenylphenol	Chloro-2-phenylphenol	≥700 ppm	• BACTERIA • VIRUS • FUNGI	10 minutes	• Domestic • Commercial
	Chlorophenol					
	Clorophene	o-benzyl-p-chlorophenol				
	o-phenylphenol	orthoxenol				
	p-phenylphenol	paraxenol				
	p-tert-pentylphenol	p-tert-amylphenol				
Iodophor	Nonylphenoxy polyethoxyethanol iodine complex	Nonoxynol iodophor a-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) iodine complex	≥ 30 ppm	• BACTERIA • VIRUS • FUNGI	10 minutes	• Domestic • Commercial
	Polyethoxy polypropoxy polyethoxy ethanol iodine complex	Iodine polyethoxy polypropoxy polyethoxy ethanol				
Chlorine releasing compound	Calcium hypochlorite		≥100 ppm	• BACTERIA • VIRUS • FUNGI	10 minutes	• Domestic • Commercial
	Sodium hypochlorite					
Organic acid	Citric acid	2-Hydroxy-1,2,3-Propanetricarboxylic Acid	≥ 25,000 ppm	• BACTERIA • VIRUS • FUNGI	5 minutes	• Domestic
			≥ 45,000 ppm	• BACTERIA • VIRUS • FUNGI	10 minutes	• Commercial
Peroxygen	Hydrogen peroxide	Hydrogen dioxide	≥ 5,000 ppm	• BACTERIA • VIRUS • FUNGI	5 minutes	• Domestic
				• BACTERIA • VIRUS • FUNGI	10 minutes	• Commercial

Table 2: Additional Active Ingredient, Minimum In-Use Concentration, Target Classes of Microorganisms, Contact Time and Use Areas For Products Intended Only For Use As Toilet Bowl Disinfectant

Category	Preferred name	Synonym	Minimum In-Use Concentration	Target Microorganism Classes	Contact Time for Disinfection and Sanitization	Use Areas[1]
Inorganic acid	Hydrogen chloride	Hydrochloric acid	≥ 95,000 ppm	• BACTERIA • VIRUS • FUNGI	10 minutes	• Domestic • Commercial

Use(s) or Purpose(s)

Statement(s) to the effect of:

For all products:

The intended drug use areas (i.e., premises for disinfection) for which the product is recommended, including one or more of the following **as supported in Table 1 or 2**:

- Domestic (i.e., for use in residential settings);
- Commercial:
    - Industrial/Institutional (i.e., for use in commercial settings, such as schools, office buildings);
    - Hospital (i.e., for use on non-critical medical devices, environmental surfaces and inanimate objects in health care facilities, such as hospitals, dental clinics, nursing homes);
    - Food Processing (i.e., for use in food processing settings, such as food processing plants and other commercial food preparation settings);
    - Barn (i.e., for use in animal housing settings, such as on farms, in poultry plants, veterinary clinics, and kennels).

The use or purpose for which the product is recommended, including one or more of the following:

Required:

- Disinfectant

Optional, ***as supported in Table 1 or 2****:*

- Kills bacteria / Bactericide / Bactericidal
- Kills viruses / Virucide / Virucidal
- Kills fungi / Fungicide / Fungicidal

Optional:

- Kills germs / Germicide / Germicidal
- Kills mould & mildew / Controls mould & mildew
- Cleaner
- Sanitizer
- Kills 99.99% of bacteria/fungi/viruses (as disinfection claim)
- Kills 99.9% of bacteria (as sanitization claim)

Unacceptable Claims and Indications for Use:

a) Statements such as non-toxic, non-irritant, safe, non-caustic, non-corrosive, harmless, etc., are not considered appropriate for disinfectant drugs.

Directions for Use

The directions for use should be consistent with the labelling recommendations provided within the guidance documents *Disinfectant Drugs* and *Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs*.

***For all products, the following should be indicated*:**

a. The types of hard surfaces to which the product may be applied (e.g., floors, walls, countertops);
b. For dilutable products, specific instructions for the preparation of the in-use dilution, in metric units of measurement[2] (e.g., millilitres per litre) or ratios (e.g., 1:256);
c. The mode of application for the product (e.g., spray, wipe, apply with a cloth or sponge);
d. A pre-cleaning statement for heavily soiled hard surfaces; a statement to the effect of one of the following is recommended:
    - For heavily soiled surface, a pre-cleaning step is required; or
    - Pre-clean heavily soiled areas.

[2] **Note:** Approximations are permitted **in addition** to the metric units as long as the information does not conflict (e.g. 1 tablespoon).

e. A contact time is required for all disinfection uses, ***as supported in Table 1 or 2.*** All sanitization uses should indicate a contact time equivalent to that required for disinfection, ***as supported in Table 1 or 2.*** All other contact times are considered to fall outside the scope of this monograph. A statement to the effect of the following is recommended:
    - Allow surface to remain wet for (X) minutes.

For products for use on hard surfaces/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):
It is recommended that a statement to the effect of the following be indicated on the labelling to remove potentially toxic residues:

- For hard 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.

For products for use in food processing and preparation areas (e.g. counters, eating and drinking utensils, and food processing equipment):
It is recommended that a statement to the effect of one of the following be indicated on the labelling:

- 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 required contact time a rinse with potable water is recommended to remove potential residues from the treated hard surfaces or objects. A statement to the effect of one of the following is recommended:

- For hard 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.

Note: *The Guidelines for Incidental Additive Submissions* should be consulted to determine the necessity of a rinse step in food processing and preparation areas. For products containing chlorine releasing compounds as the single active ingredient category, a rinse is not required if the product is used at or below an in-use concentration of 200 ppm. For products which exceed this in-use concentration, an appropriate rinse statement should be indicated on the labelling.

For products for use in animal housing areas (e.g., floors, walls, cages, and animal equipment) within industrial/institutional and barn premises (e.g., farms, poultry plants, veterinary clinics, and kennels):

It is recommended that statements to the effect of the following be indicated on the labelling:

- Remove all animals/poultry and their feed from premises prior to disinfection;
- Remove all heavy soil, such as urine and fecal matter, from hard 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 hard 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 required contact time a rinse with potable water is recommended to remove potential residues from the treated hard 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.

For products for use on non-critical medical devices in hospital or healthcare settings (e.g., stethoscopes, hospital beds, and wheel chairs):

It is recommended that a restrictive use statement to the effect of the following be indicated on the labelling:

- 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.

***For all products, the following directions for use should also be indicated on the labelling*:**

a. Warning statements; the following statements should be indicated:
   - Read the label before using.
   - Keep out of reach of children.

b. Precautionary statements, when applicable and appropriate for the potential hazard of the product, including:
   - Signal words and hazard statements
   - Personal protective equipment statements
   - First aid statements
   - Physical and chemical hazards statements

c. Storage instructions

d. Disposal instructions

***For all products, the following regulatory information must be indicated on the labelling*:**

a. The name and address of the manufacturer of the product, including a toll-free phone number and website for consumers to be able to report complaints and provide feedback. If the address of the manufacturer is not in Canada, then the name and address of the importer must be indicated on the label.

b. The identity and percent nominal concentration of each active ingredient in the product, expressed as a percentage on a weight-per-weight basis (% w/w).

c. The net contents of the product in its marketed packaging.

d. A placeholder for the lot number.

e. A placeholder for the expiration date for all commercial products.

f. A placeholder for the drug identification number (DIN).

Non-Medicinal Ingredients

Non-medicinal ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database. For additions or modifications to the NHPID, an NHPID Issue Form should be completed and submitted to Health Canada in advance of an application for a disinfectant drug.

Note: The presence of non-medicinal ingredients should not adversely affect the efficacy or safety of the active ingredient(s).

Specifications

This monograph describes requirements that are specific for disinfectants 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). Fabricators, packagers/labellers, distributors, importers and testers of disinfectants which meet the regulatory definition of an “antimicrobial agent” are not required to obtain an establishment licence or meet Good Manufacturing Practices (GMP) compliance requirements; however, they are still expected to meet the provisions of section 8 of the *Food and Drugs Act*, which denotes the prohibition on selling drugs manufactured under unsanitary conditions or that are adulterated. To support compliance with this regulatory requirement, a voluntary standard was developed by Health Canada: *Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Surfaces and Certain Medical Devices*, Version 2 (Guide-0049).

All other requirements described in the *Food and Drug Regulations*, as applicable, must be met. However, as outlined in the guidance document, entitled *Disinfectant Drugs*:

- Any colouring agent may be used in disinfectant drugs, unless there is a safety issue related to its use.
- Health Canada considers the highest degree of purity requirement specified in section C.01.011(4) of the *Food and Drug Regulations* not to be applicable to disinfectant drugs.The extension of the upper active ingredient limit beyond 110.0% of the nominal active ingredient concentration claimed on the label is considered acceptable for liquid disinfectants containing sodium hypochlorite as their active ingredient due to their rapid degradation and inherent instability. For these products, an over formulation not exceeding 25.0% of the nominal active ingredient concentration claimed on the label is permitted, which is expected to ensure that the product remains effective for the duration of the product's shelf life (i.e., a minimum of 1 year).

References Cited

Health Canada 2014. Guidance Document – *Disinfectant Drugs*. January 2014. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disin_desin-eng.php [accessed 2014-11-27].

Health Canada 2014. Guidance Document - *Management of Disinfectant Drug Applications*. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/mdda-gpdd-eng.php [accessed 2014-11-27].

Health Canada 2014. Guidance Document - *Safety and efficacy requirements for hard surface disinfectant drugs*. Available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/hsdd-ddsd-eng.php#a21 [accessed 2014-11-27].

Health Canada 2010. *Guidelines for Incidental Additive Submissions*. Available at: http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/guide_incidental_addit_indirects-eng.php [accessed 2014-11-27]

Health Canada 2007. Hard Surface Disinfectants Monograph. [Original publication August 2007]

Health Canada 2007. Toilet Bowl Disinfectant Cleaners Monograph.. [Original publication August 2007]

Health Canada 1998. *Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products*. Available at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/pol_nonther_comp-eng.php [accessed 2014-11-27].

References reviewed

Centers for Disease Control and Prevention 2008. Healthcare Infection Control Practices Advisory Committee (HICPAC) *Guideline for Disinfection and Sterilization in Healthcare Facilities*. Available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf [accessed 2014-11-27].

Health Canada 2014. Drug Product Database (online and in-house). Online available at: http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp [accessed 2014-11-27].

United States Environmental Protection Agency 2014. National Pesticide Information Retrieval System. Available at: http://ppis.ceris.purdue.edu/ [accessed 2014-11-27].

Rutala, W.A., Gergen, M.F., and Weber, D.J. 2012. Efficacy of improved hydrogen peroxide against important healthcare-associated pathogens. Infection Control and Hospital Epidemiology, 33(11): 1159-1161.

Rutala, W.A., and Weber, D.J. 2013. Disinfectants used for environmental disinfection and new room decontamination technology. American Journal of Infection Control, 41 (2013) S36-S41.

Russell, Hugo & Ayliffe's Principles and Practice of Disinfection, Preservation and Sterilization, 5th Edition", December 2012.