

Hard surface disinfectants monograph

I. Description

This monograph applies to antimicrobial products which are classified as disinfectant drugs and specifically to products which are intended to be used as environmental hard surface disinfectants in health care facilities, food processing plants and/or domestic dwellings. The medicinal, i.e., active ingredients and their concentrations in Category IV products are restricted to those specified in this monograph. The medicinal, i.e., active ingredients should be identified on product labelling by the names given in Table 1 of this monograph (both preferred names and synonyms are considered acceptable).

This monograph does not apply to:

- a. disinfectant products to be used on critical or semi-critical medical devices or instruments, including contact lenses (ref. to Category IV product monograph for contact lens disinfectants);
- b. to products with claims for efficacy against:
 - spores, as a sporicide, or as a sterilant
 - pathogens, as a high-level disinfectant
 - *Mycobacterium* species, including *M. tuberculosis*
 - the Human Immunodeficiency Virus (HIV)
 - the Hepatitis B and C Viruses (HBV and HCV)

II. Pharmaceutical quality

- a. All medicinal (active) and nonmedicinal (inactive) ingredients and finished product, should as a minimum meet the specifications of Schedule B or equivalent standard. In the absence of a Schedule B standard, testing should be adequate to demonstrate the product's identity, potency, purity and quality.

III. Ingredients

a. Single medicinal ingredient categories

- i. Quaternary ammonium compounds
- ii. Phenolics
- iii. Iodophors
- iv. Chlorine releasing compounds

A list of acceptable single medicinal ingredients for Category IV hard surface disinfectants is provided in Table 1.

b. Combinations of medicinal ingredients

- Combinations of any of the medicinal ingredients from the same category are permitted provided that the total in-use concentration of the combined ingredients is at the minimum stated in section IV) d) iv).
- Combinations of any of the medicinal ingredients from different categories listed in Guidance are permitted provided that the ingredient(s) from one of the categories is present at the minimal in-use concentration as stated in section IV) d) iv), and that the ingredients do not interact in a manner that reduces the disinfectant activity.

c. Nonmedicinal ingredients

Nonmedicinal ingredients should be restricted to the substances that are necessary for the formulation. Their concentration should not exceed the minimum required to provide their intended effect. Their presence should not adversely affect the efficacy or safety of the medicinal ingredient(s) and they should not interfere with assays and tests for the medicinal ingredients.

IV. Labelling

- a. This monograph describes the requirements that are specific to hard surface disinfectant drug products. Other requirements described in the *Food and Drugs Act* and *Regulations* should also be met.

b. Unacceptable claims

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

c. Indications

All products should indicate:

- i. for use in a health care facility (e.g, hospitals, dental clinic, nursing homes), a food processing plant, a commercial setting (i.e., schools, offices), and/or a residential home (i.e., domestic settings); and
- ii. one or more of the following as applicable to the product:
 1. disinfectant / disinfectant cleaner
 2. kills bacteria (bactericide)
 3. kills viruses (virucide)
 4. kills fungi (fungicide)

d. Directions for use

- i. For all products complete directions for use as a disinfectant for inanimate environmental surfaces including:

- types of surfaces (e.g, floors, walls, countertops);
 - specific instructions for the preparation of the in-use dilution in metric units of measure;
 - mode of application;
 - a contact time of 10 minutes if the product is to be rinsed or wiped off;
 - a warning to the effect that all surfaces and/or objects coming in contact with children at the mouthing stage of development, are to be rinsed.
- ii. The following additional statement should be indicated if the product is to be used in a food processing establishment:
- All surfaces that come into contact with food are to be rinsed with potable water after disinfection.
- Note:** For disinfectants containing only chlorine-releasing medicinal ingredients, a rinse is not required if used at a concentration = 200 ppm.
- iii. The following additional statement should be indicated if the product contains phenolic compound(s) and is for use in health care facilities:
- not to be used in hospital nurseries.
- iv. **In-use solution concentrations**
1. Quaternary ammonium compounds = 450 ppm
 2. Phenolics = 700 ppm
 3. Iodophors = 30 ppm
 4. Chlorine = 100 ppm
- v. **Warnings and first aid information**
1. For all products, warnings, precautionary statements and first aid information should be appropriate to the hazard.
 2. For products intended to be used in food processing plants, the following statement:
 - avoid contamination of food.

Table 1 Single medicinal ingredients		
Category	Preferred name	Synonym
Quaternary ammonium compounds	Alkyl ethyl benzyl dimethyl ammonium chloride	
	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 ammonium chloride	Chloride dioctyl dimethylammonium
	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
Phenolics	Chloro-ortho-phenylphenol	Chloro-2-phenylphenol
	Chlorophenol	
	Clorophene	o-benzyl-p-chlorophenol
	o-phenylphenol	orthoxenol
	p-phenylphenol	paraxenol
	p-tert-pentylphenol	p-tert-amylphenol
Iodophors	Nonylphenoxy polyethoxyethanol iodine complex	Nonoxynol iodophor a-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) iodine complex
	Polyethoxy polypropoxy polyethoxy ethanol iodine complex	Iodine polyethoxy polypropoxy polyethoxy ethanol
Chlorine releasing compounds	Calcium hypochlorite	
	Sodium hypochlorite	