

Toilet Bowl Disinfectant Cleaners 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 toilet bowl disinfectant cleaners 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 products with claims for efficacy against:

- a. spores, as a sporicide, a sterilant, or a high-level disinfectant
- b. Mycobacterium species, including *M. tuberculosis*
- c. the Human Immunodeficiency Virus (HIV)
- d. the Hepatitis B and C Viruses (HBV and HCV)

II. Pharmaceutical Quality:

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. Hydrogen chloride

A list of acceptable single medicinal ingredients for Category IV toilet bowl disinfectant cleaners is provided in Table 1.

b. Combinations of Medicinal Ingredients

- i. 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) ii).
- ii. Combinations of any of the medicinal ingredients from different categories listed in Table 1 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) ii), and that the ingredients do not interact in a manner that reduces the disinfectant activity.

Note: Phosphoric acid can be considered to be a medicinal ingredient if used in a combination product and if the manufacturer has data available which show that it is essential for the efficacy of the product.

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 toilet bowl disinfectant cleaners for use in healthcare facilities, food processing plants and/or domestic dwellings. 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 toilet bowl disinfectant cleaner including:
 - specific amount/volume of disinfectant to be used
 - mode of application;
 - a contact time of at least 10 minutes followed by a flush of the toilet;
- ii. **In-use Solution Concentrations**
 1. Quaternary ammonium compounds = 450 ppm
 2. Hydrogen chloride = 9.5%



iii. **Warnings and First Aid Information**

For all products, warnings, precautionary statements and first aid information should be appropriate to the hazard.

| 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 |
| | Diocetyl 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 |
| Inorganic Acid | Hydrogen chloride | Hydrochloric acid |
| Chlorine releasing compounds | Calcium hypochlorite | |
| | Sodium hypochlorite | |