



APVMA GUIDE FOR DEMONSTRATING EFFICACY OF POOL AND SPA SANITISERS

1. Introduction

For many years, disinfection of swimming pools and spa pools has relied mainly on chemical sanitisers based principally on chlorine and bromine. The efficacy of these traditional sanitisers is well established with regard to different kinds of pathogenic microorganisms. New types of chemical sanitisers however, which lack that established record, must be shown to be effective against pathogenic microorganisms under conditions found in swimming pools and spas before they can be approved for use.

This document is a guide setting out how applicants could demonstrate that a proposed new pool and spa sanitiser would satisfy the APVMA's efficacy criteria as stated in section 2. While meeting the performance characteristics set out in sections 3 and 4 can be expected to satisfy the APVMA's efficacy requirements, the APVMA is prepared to consider alternative scientific information and argument aimed at satisfying the efficacy criteria.

Note that in addition to efficacy criteria, a new sanitiser must also meet the APVMA's safety criteria relating to human health and to the environment. For example, there should be no adverse impact or toxic effect of the sanitiser or its by-products that exceeds health standards on bathers with either short term or extended immersion in water treated with the sanitiser. Information on toxicology data requirements and other of the APVMA's requirements can be found on its website at http://www.apvma.gov.au/guidelines/ag_manual.shtml .

2. Efficacy Criteria for Pool and Spa Sanitisers

Applicants must be able to establish that the proposed new sanitiser is effective against the key pathogens in the major classes of human pathogenic microorganisms commonly found in swimming pool and spa pool environments, namely bacteria, protozoa, viruses and fungi. As a general guide, applicants must be able to establish that the product is equivalent in efficacy to registered sanitisers based on hypochlorous acid/hypochlorite against these classes of microorganisms.

In addition to efficacy equivalent to hypochlorous acid/hypochlorite as demonstrated in laboratory and field tests (see Table 1 in Section 3 – Guidelines for Laboratory Testing and Section 4 – Guidelines for Field Testing), a swimming pool or spa pool sanitiser or disinfectant process must have the following general performance features or properties.

- An effective residual concentration of sanitiser can be maintained in the body of the pool to provide continuous disinfection within the water at all times.
- The concentration of the residual sanitiser (or its principal components if there is more than one active constituent) is capable of being measured using a field test kit or other simple method that can be properly managed by an average home pool owner.
- The sanitiser is capable of supplementary dosing if measured levels are found to be below the recommended effective concentration.
- A minimum efficacy threshold concentration has been identified for the sanitiser so that a known efficacy safety margin can be established for normal operating concentrations.
- For sanitisers containing more than one active constituent, the relative contributions of each principal active constituent to the overall efficacy have been identified.

It is the responsibility of the applicant to prove, through independent assessment, that a disinfectant or disinfecting process can meet these criteria.

3. Guidelines for Laboratory Testing Phase

As a first step, a sanitiser or disinfecting process must be shown to be effective under defined laboratory conditions against key indicator organisms within the major classes of pathogenic microorganisms associated with pools and spas. Satisfactory efficacy under laboratory conditions can be demonstrated by following the testing guidelines below.

- Tests, including preparation of materials and analysis of test samples, are to be carried out by a NATA registered or similarly accredited laboratory having no affiliation with or connection to the applicant. Assay methods for each type of test should be well established and reproducible by the host laboratory.
- Tests shall be carried out at a pH of 7.3 and at a temperature consistent with intended use conditions, specifically 25°C for swimming pools and 35°C for spas.
- During disinfection testing, no chemical with disinfecting properties other than the test sanitiser (which may be a mixture of two or more active constituents) is to be present in the water.
- A minimum efficacy threshold needs to be established and for products with more than one active constituent using different modes of action (for example, metal ions and accompanying oxidizers) the independent contributions of the principal components to overall efficacy need to be demonstrated. (For an example protocol, see Table 2 in ‘Special Instructions for testing silver and copper based sanitisers’.)

- Each test should consist of a minimum of 3 separate trials with each trial having its own controls. It is recommended that each trial should consist of at least 6 to 10 replicate samples.

The performance characteristics of an effective sanitiser against the recommended test organisms are shown below in Table 1.

Table 1

Test Organism	Number of log₁₀ reductions to be achieved	Time of exposure to test sanitiser at normal concentration during which reduction is to be achieved
Bacteria		
<i>Pseudomonas aeruginosa</i>	4	30 seconds
<i>Legionella pneumophila</i>	4	30 seconds
Fungi		
<i>Trichophyton mentagrophytes</i> (conidia)	5	10 minutes
Viruses		
Adenovirus	4	5 minutes
Rotavirus	4	5 minutes
Protozoa		
<i>Naegleria fowleri</i> (cysts)	4	30 minutes
<i>Giardia muris</i> (cysts)	3	45 minutes

Results from other efficacy studies with other indicator organisms may be accepted by the APVMA provided that additional scientific information and argument can satisfy the APVMA that those studies prove the product meets the efficacy criteria in section 2.

Note that a fee will apply for the evaluation of the laboratory test phase by the APVMA. (Contact the APVMA for more information.)

Special instructions for testing silver and copper ion based sanitisers

Phosphate buffers should not be used in disinfection tests since phosphate complexes with copper ions and would interfere with test results.

Disinfection test periods should not be terminated by using chelating agents to sequester copper and silver ions because test results could be invalidated. Chelating agents are not sufficiently specific for copper or silver to avoid reacting with other metal ions as well. Removal of calcium ions, for example, is known to interfere with the infectivity of some viruses (including rotavirus), and there is evidence that *Naegleria fowleri* is adversely affected by chelating agents. As an alternative, it is recommended that at least a 100 fold dilution method with appropriate culture medium be used to terminate disinfection test periods and that the sample be progressed as quickly as possible to the plating and incubation stage to further dilute the concentration of metal ions.

Copper and silver ion based sanitisers are necessarily used in conjunction with oxidizers, usually either chlorine or one or more of the peroxygen compounds. It is necessary to establish a minimum concentration threshold for efficacy as well as establish how much of the overall efficacy is contributed by the metal ions and how much by the oxidizer. These questions can be answered to the APVMA's satisfaction by a series of experiments on *Pseudomonas aeruginosa* that test different ratios of the combined active constituents and different concentrations of the intended ratio of the active constituents. For example, if the proposed operating concentrations of the metal ions and oxidizer are M and O respectively, a suitable trial design is shown below in Table 2.

Table 2

Metal Ion Series	Oxidizer series	Efficacy Threshold
Nil M with O	Nil O with M	–
0.2 M with O	0.2 O with M	0.2 of [M with O]*
0.4 M with O	0.4 O with M	0.4 of [M with O]*
0.6 M with O	0.6 O with M	0.6 of [M with O]*
0.8 M with O	0.8 O with M	0.8 of [M with O]*
M with O	O with M	–
Control (Nil M & O)	Control (Nil M & O)	Control (Nil M & O)

* i.e. 0.2 or 0.4 etc. times the recommended operating concentrations of metal ions and oxidiser

It may be necessary to complete a preliminary range finding experiment to determine how many cells should be used for each test sample so that all are not killed and a reportable value is obtained. The reported value for each sample should be the log reduction in viable bacteria after 1 minute of exposure. The exposure period can be varied if necessary to obtain meaningful results. (For the final efficacy threshold, the reported value should also be linked using an additional test, if necessary, to the 30 second performance period for *Pseudomonas aeruginosa*.)

Note that when more than one type of metal ion is used in the system (for example – copper, silver and zinc), it is not necessary to test each metal ion separately. However, the mixture of metal ions in the intended ratio of the marketed product must be used. In the same way, if a mixture of oxidizers is formulated or recommended for the final product, the same mixture as intended for the marketed product must be used as the “oxidizer” in the tests.

4. Guidelines for the Field Testing Phase in a Full Size Pool or Spa

After performance in the laboratory efficacy testing phase has been accepted as adequate by the APVMA and after the APVMA has already been satisfied that water containing the sanitiser at its recommended concentration is safe for human exposure during swimming and bathing, the proposed new sanitiser needs to be tested in a field situation in a full size

swimming pool (or spa pool if applying to be registered for spa pool sanitation) that has a significant bather load. A busy public pool and/or spa are preferred for these field tests.

The trials should be conducted by an independent agency accredited by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or equivalent organization with which JAS-ANZ has a memorandum of understanding. Results should be analyzed and reported without intervention by the applicant.

The aim of the field test is to demonstrate the efficacy of the swimming pool or spa pool sanitiser or disinfection process under actual use conditions. The applicant should design a suitable test protocol of not less than six months duration on the type of pool/spa in which the sanitiser or disinfecting process is to be used. The protocol should be designed to provide an accumulation of evidence that clearly shows compliance with relevant guidelines for control of swimming pool and spa pathogenic microorganisms under field conditions. See Table 3 below for guidelines on effective sanitiser performance characteristics during field testing.

Table 3

Test Organisms	Test Method	Maximum Count Allowable
Heterotrophic Colony Count	Pour plate method. Incubation for 48 hours at 35°C following Australian Standard Method AS4276.3.1 – 1995	100 Colony Forming Units (CFU) per mL
Thermotolerant coliforms	Australian Standard Method AS 4276.6 – 1995 (MPN Method) or AS 4276.7 – 1995 (Membrane Filtration Method)	Nil per 100 mL
<i>Pseudomonas aeruginosa</i>	Australian Standard Method AS 4276.12 – 1995 (MPN Method) or AS 4276.13 – 1995 (Membrane Filtration Method)	Nil per 100 mL

The following minimum methodology and features should be incorporated into the trial design and should be found to be satisfactory by the APVMA prior to commencement of the trial.

Note that fees will apply to approval of the test protocol and to issuance of a permit for the field trial. (Contact the APVMA for more information.)

1. Features of the Trial

- pool design – dimensions, volume and location (indoor or outdoor)
- water distribution and circulation pattern
- turnover rates of the pool(s) under test, and for spa pools, details of water dumping schedule and refill
- balance tank details
- method of dosing of the sanitiser (and if chlorine is part of the system, whether chlorine is stabilised or unstabilised)
- details of other chemicals used
- filtration, flocculation and backwashing details
- details of rainfall events (for outdoor pools)
- details of laboratories used
- methodology for all microorganism efficacy tests and key chemical assays
- appropriate Material Safety Data Sheets for active constituents handled as concentrates

2. Test Protocol

- water sampling location(s) for microorganisms and chemicals, sample replication and transport methodology
- sampling design and strategy
- details of other parameters at sampling
- bather load for 1 hour period prior to sampling
- concentration of sanitiser at time of sampling
- measurement of pH at time of sampling
- measurement of reserve (total) alkalinity
- concentration of any other relevant chemical
- millivolt equivalence of disinfection agent if it is proposed to control the sanitiser using redox potential