Therapeutic Goods (Standard for Disinfectants) Order 2018 (Therapeutic Goods Order X)

I, Tracey Duffy, as delegate of the Minister for Health, make the following Order.

Dated

Tracey Duffy
Acting First Assistant Secretary
Medical Devices and Product Quality Division
Department of Health

Contents

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Disinfectants) Order 2018*.

(2) This instrument may also be cited as Therapeutic Goods Order X, or TGO X.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 April 2019.	1 April 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 10(1) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in the definitions section of the Act, including the following:

(a) batch;
(b) container;
(c) current Poisons Standard;
(c) label;
(e) primary pack;

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

antibacterial clothes preparation means a disinfectant that is represented to be capable of reducing the number of viable micro-organisms in water in which clothes are soaked, washed or rinsed.

antibiotic means a substance which is a selective antimicrobial agent (other than a disinfectant, antiseptic or substance used solely as an antineoplastic) that, on application to living tissue or by systemic administration, kills or prevents the growth of susceptible micro-organisms.

antimicrobial soap has the same meaning as "skin disinfectant".

antiseptic has the same meaning as in the Regulations.

antiseptic soap has the same meaning as "skin disinfectant".

Approved name means that name for an ingredient which is included in the "Australian Approved Names List".

Australian Approved Names List has the same meaning as in the Regulations.

batch number means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, to identify uniquely that batch, and from which it is possible to trace that batch through all stages of manufacture and distribution.

biocide means a physical or chemical agent that kills some or all types of micro-organisms.

common name in relation to a substance listed in Column 1 of Schedule 3 to this order means the name or names listed opposite that substance in Column 2 of that Schedule. (It is the name that is to be used on the label).

disinfectant has the same meaning as in the Regulations.

expiry date has the same meaning as in the Regulations.

fungicide has the same meaning as in the Regulations.

hard surface disinfectant is a collective term used for household/commercial grade and hospital grade disinfectants.

hospital grade disinfectant has the same meaning as in the Regulations.

household/commercial grade disinfectant has the same meaning as "household grade disinfectant" in the Regulations.

hygienic hand rub has the same meaning as skin disinfectant.

hygienic hand wash has the same meaning as skin disinfectant.

label dilution means the dilution (if any) of the disinfectant recommended by the manufacturer on the label for use.

main label means:

(a) where there are two or more labels or two or more portions of a label, that label or portion of the label where the trade name or, where there is no trade name, the name of the goods is more or most conspicuously shown; or

(b) where the trade name or, where there is no trade name, the name of the goods is equally conspicuous on two or more labels or portions of a label - either of such label or portion.

Minimum Effective Concentration (MEC) is the minimum concentration of a biocide product which achieves the claimed microbiocidal activity. The MEC is determined by dose response testing.

Minimum Recommended Concentration (MRC) is the minimum concentration of a biocide product at which efficacy has been demonstrated, as recommended on the label. The MRC is not necessarily an MEC as determined by dose response testing.

name and address in respect of a sponsor or manufacturer of a disinfectant means -

(a) where the manufacturer or sponsor has a registered name, that registered name; or

(b) in the case of a manufacturer or sponsor not having a registered name, the name of the manufacturer or sponsor of the disinfectant, including a manufacturer whose place of business is outside Australia;

and

(c) in the case of a manufacturer or sponsor having a registered name, the city, town or locality in which the registered office or registered place of business is situated; or

(d) in the case of a manufacturer or sponsor not having a registered name, the address of the principal place of business of that manufacturer or sponsor including where applicable, the street number, street name, the town or city, and the State or Territory in Australia or the name of the overseas country, as the case may be but not including a post office, cable, telegraphic or code address.

pass means to meet or exceed the minimum requirement specified in subsection 7(8) in relation to the prescribed test or where other tests are involved for other biocidal activities, the criteria specified in or for those tests.

prescribed test means the "TGA Disinfectant Test" described in Schedule 1 to this instrument.

Regulations means the *Therapeutic Goods Regulations 1990*, as in force from time to time.

sanitary fluid means a chemical agent that is represented to be suitable for use in the charging of sanitary units used for the storage or disposal of human waste and which is not represented to be suitable for any other use.

sanitary powder has the same meaning as sanitary fluid.

sanitiser means a chemical agent that is represented to be suitable for use in the reduction of pathogenic or food-spoilage micro-organisms to a sanitary level on surfaces with which food for human consumption may come in contact.

Note: Products which implicitly or explicitly reduce micro-organisms, other than viruses, to a sanitary level and which, while making specific claims against a limited number of micro-organisms, are the subject of user specifications, or are subject to a recognised industry standard and are not for the retail market, will not be regarded as a disinfectant provided they do not claim to be a disinfectant.

skin disinfectant means an antiseptic that is intended for application to intact, healthy skin to prevent the transmission of transient or resident skin bacteria from person to person or from a surgical operation site to underlying tissues. Skin disinfectants include, but are not restricted to, antimicrobial and antiseptic soaps, hygienic hand washes, hygienic hand rubs, surgical hand rubs, scrubs and washes.

sporicide has the same meaning as in the Regulations.

suitable means, when used in respect of a test to be passed, that the test is consistent with the recommendations and requirements in this instrument.

surface spray disinfectant means a disinfectant that is represented to be suitable for use undiluted as a spray and which is not represented to be suitable for any other method of use.

surgical hand rub has the same meaning as skin disinfectant.

surgical scrub has the same meaning as skin disinfectant.

surgical wash has the same meaning as skin disinfectant.

TGA means the Therapeutic Goods Administration.

trade name has the same meaning as in the Regulations.

tuberculocide has the same meaning as in the Regulations.

use by date has the same meaning as expiry date.

virucide means a chemical agent that renders a virus non-infective.

5 Application

(1) This instrument applies to disinfectants, sanitisers and sanitary preparations except:

(a) disinfectants and sterilants that are medical devices;

(b) sterilant gases;

(c) antiseptics and skin disinfectants;

(d) antibiotics;

(e) a product that is represented to be suitable for antifungal use only;

(f) a disinfectant or sanitiser registered under the *Agricultural and Veterinary Chemicals Code Act 1994* for which no claim or representation for disinfectant use is made, other than a use for which the disinfectant is registered under that Act;

(g) a disinfectant or sanitiser that is represented to be suitable for the treatment of water only;

(h) contact lens care products.

6 Formulation and physical/chemical properties of Disinfectants

(1) The formulation of the disinfectant must be comprised of ingredients that have an Approved name.

(2) The physical form of the disinfectant must be appropriate for its intended application.

7 Standards for performance of Disinfectants

(1) Where the directions for use on a label attached to or appearing on the container or a primary pack of a therapeutic good represent it to be a *hospital grade disinfectant*, the minimum performance requirement must apply as follows:

(a) where the disinfectant is for general purpose use on surfaces:

(i) if tested in accordance with the prescribed test it must, pass the prescribed test under the conditions specified in **Option A** or **Option B** of the prescribed test, or an equivalent test as specified in Schedule 2; and

(ii) pass a suitable bactericidal carrier test as specified in Schedule 2; and

(iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests as specified in Schedule 2 only where a claim is made in respect of any of these actions; and

(iv) pass each of the tests in (i), (ii), and (iii) according to the conditions specified or claimed on the label, if any;

(b) when for use as a surface spray it must:

(i) pass a suitable bactericidal carrier test as specified in Schedule 2; and

(ii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests as specified in Schedule 2 only where a claim is made in respect of any of these actions; and

(iii) pass each of the tests in (i) and (ii) according to the conditions specified or claimed on the label.

(c) where the disinfectant is presented as a cloth wipe impregnated with disinfectant, and intended for single use or multiple use for disinfection of surfaces, it must:

(i) if tested in accordance with the prescribed test, pass the prescribed test under the conditions specified in Option A or Option B of the prescribed test or a suitable equivalent test as specified in Schedule 2, when the test is carried out on the product after extraction from the wipe;

(ii) pass a suitable (single or multiple use) simulated in-use test as specified in Schedule 2;

(iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests as specified in Schedule 2 only where a claim is made in respect of any of these actions; and

(iv) pass each of the tests in (i), (ii), and (iii) according to the conditions specified or claimed on the label, if any.

(d) where the disinfectant is presented as a cloth wipe or sponge impregnated with disinfectant, and intended for multiple use for disinfection of surfaces and the ingredient that is active cannot be expressed, it must:

(i) pass a simulated in-use test as specified in Schedule 2 after the product has been subjected to a re-use protocol.

(2) Where the directions for use on a label attached to or appearing on the container or primary pack of a therapeutic good represent it to be a *household/commercial grade disinfectant*, the minimum performance requirement must apply as follows:

(a) where the disinfectant is for general purpose use:

(i) if tested in accordance with the prescribed test it must, pass the prescribed test under the conditions specified in **Option C** of the prescribed test or a suitable equivalent test as specified in Schedule 2; or

(ii) pass a suitable bactericidal carrier test as specified in Schedule 2; and

(iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests as specified in Schedule 2 only where a claim is made in respect of these actions; and

(iv) pass each of the tests in (i), (ii) and (iii) according to the conditions specified or claimed on the label, if any;

(b) where the disinfectant is for use as a surface spray it must:

(i) pass a suitable bactericidal carrier test as specified in Schedule 2; and

(ii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests as specified in Schedule 2 only where a claim is made in respect of any of these actions; and

(iii) pass each of the tests in (i) and (ii) according to the conditions specified or claimed on the label.

(c) where the disinfectant is presented as a cloth wipe impregnated with disinfectant, and intended for single use or multiple use for disinfection of surfaces, it must:

(i) if tested in accordance with the prescribed test, pass the prescribed test under the conditions specified in Option C of the prescribed test or a suitable equivalent test as specified in Schedule 2, when the test is carried out on the product after extraction from the wipe

(ii) pass a suitable (single or multiple use) simulated in-use test;

(iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests as specified in Schedule 2 only where a claim is made in respect of any of these actions; and

(iv) pass each of the tests in (i), (ii), and (iii) according to the conditions specified or claimed on the label, if any.

(d) where the disinfectant is presented as a cloth wipe or sponge impregnated with disinfectant, and intended for multiple use for

disinfection of surfaces and the ingredient that is active can't be expressed, it must:

(i) pass a simulated in-use test after the product has been subjected to a re-use protocol.

(3) Where different uses for a disinfectant are specified in a label on the container or primary pack containing the disinfectant and different conditions are recommended on the label for each use, each label claim should meet the prescribed test for that type of use. The test should be carried out at the highest dilution recommended on the label for that use and at the end of the shelf life of the disinfectant prepared for that use.

(4) A disinfectant must not be regarded as having failed to pass the prescribed test unless:

(a) it fails to pass the prescribed test on each occasion of the 3 occasions of testing; or

(b) where it fails to pass the prescribed test on 1 or 2 of the 3 occasions of testing and the prescribed test is again carried out, it fails to pass the prescribed test when it again fails any of the three occasions of the test.

(5) A disinfectant must have adequate stability data to support the assigned shelf life. The minimum requirements to support physical stability, chemical stability and microbial efficacy must be demonstrated in accordance with the testing procedures set out in Schedule 2.

(a) A disinfectant must not have a shelf life greater than 5 years except:

(i) There must be no requirement for products intended only for the export market to carry an expiry date if the country of destination does not require expiry dating.

(ii) If the country of destination requires expiry dating, then extrapolation of stability data to support shelf life should conform with the local regulatory requirement of that country, and not necessarily to the Australian requirement.

(6) A disinfectant must have adequate data demonstrating the product is safe with respect to toxicity. Toxicity data should cover, where relevant:

(a) Potential hazards to the user through accidental body contact;

(b) Acute oral toxicity in concentrations equivalent to those likely to be encountered in use;

(c) Inhalation toxicity, skin irritation, sensitisation and eye irritation;

(d) Haemocompatibility, sub-chronic toxicity, mutagenicity and carcinogenicity;

(e) Ecotoxicological considerations; and

(f) Other forms of toxicity that may present a hazard.

8 Standards for Packaging and Labelling of Disinfectants

Packaging

(1) A disinfectant must be enclosed in a container.

(2) The container must be suitably designed to ensure the adequate protection and containment of the contents. If the disinfectant is either a scheduled poison and/or classified as a dangerous good then the container must comply with the Poisons Standard and/or the Australian Dangerous Goods Code (edition 7.6).

Labelling

(3) Labelling for all goods covered by this order must comply with the requirements of the Poisons Standard except that where there is a conflict the requirement specified in this order must have precedence.

(4) The container and any primary pack containing a disinfectant, sanitiser or sanitary product must be labelled with the following particulars:

(a) except as provided in subparagraphs 8(4)(a)(i) and (ii), a *common name* of the disinfectant, sanitiser or sanitary product as listed in Column 2 to Schedule 3 to this order:

(i) for a sanitiser, the common name for an antibacterial clothes preparation may be also used instead of the common name for the sanitiser;

(ii) each of the following common names must be used on its own and not in conjunction with any other common name:
sanitary fluid; and
sanitary powder.

(b) the Approved name of the ingredient active against pathogenic or food-spoilage micro-organisms or, in the case of a disinfectant containing more than one such ingredient, the Approved name of each ingredient;

(c) the quantity or proportion of each ingredient active against pathogenic or food-spoilage micro-organisms, together with, where applicable, a statement of the proportion of available chlorine, bromine or iodine; this proportion must be expressed as a percentage of the total mass or volume of the disinfectant;

(d) the quantity of disinfectant;

(e) the batch number of the disinfectant immediately preceded by the words “Batch”, “Batch Number”, “Batch No.”, “Lot”, “Lot Number”, “Lot No.”, “Lot Code”, or by words having a similar meaning or by the symbol “B”, Ⓑ or “(B)”;

(f) the expiry date or use by date of the disinfectant, immediately preceded by the words “Expiry date”, “Expiry”, “Exp.” or “Use by” or words or an internationally recognisable symbol (such as the hour glass) having the same meaning;

Note: The provision for the use of a symbol does not include provision by way of a barcode at this time.

(g) the name and address of the manufacturer or sponsor of the disinfectant;

(h) clear and adequate instructions for all intended uses of the disinfectant, including:

(i) the method of use of the disinfectant and a clear warning in any case where a danger exists if an incorrect method of use is employed;

(ii) except as provided in subsections 8(7) and 8(8) the words "Do not mix with detergents or other chemicals";

(iii) subject to subsection 8(9), a statement of the dilution or dilutions of the disinfectant in water or other diluent to be employed or the words "Use undiluted"; and

(iv) in the case of a disinfectant requiring preparation before use, instructions for correct preparation, use and storage conditions of the preparation should be supplied.

(v) the following words:

(i) Hard surface disinfectant only: and

(ii) Not to be used on skin.

(i) clearly identified potential hazards through accidental body contact.

(5) Household grade disinfectants and commercial grade disinfectants are not to be labelled as "hospital grade".

Specifications, Modifications and Exceptions

(6) The words required by subparagraphs 8(4)(h)(i) will, in the case of a hospital grade disinfectant, indicate that it is not intended to be used on medical devices or other therapeutic goods.

(7) The words required by subparagraphs 8(4)(h)(ii) may be followed by the word "except", the name of a specific substance or product and the words "as directed below".

(8) Subparagraphs 8(4)(h)(ii) and (iii) do not apply in the case of a surface spray disinfectant.

(9) For a liquid disinfectant, the statement of dilution (if applicable), referred to in subparagraph 8(4)(h)(iii) to be employed must be either:

(a) "1 in N" meaning that 1 part of the disinfectant is made up with water or other diluent to a total volume of N parts; or

(b) "1: N" meaning that 1 part of the disinfectant is added to N parts of water or other diluent.

(10) In the case of a hospital grade disinfectant, the statement of dilution referred to in subparagraph 8(4)(h)(iii) must not contain directions for the preparation of a dilution of the disinfectant from another such dilution.

(11) The particulars referred to in paragraphs 8(4)(a), (b), (c) and (d) must be written on the main label.

(12) The particulars referred to in subsection 8(4) must be written:

(a) in the English language;
(b) on the outer face of the label;
(c) in durable and legible characters having a letter height of not less than 1.0 millimetre;
(d) in a metric unit of measurement; and
(e) in a colour or colours that will afford a distinct contrast to the background colour and be clearly visible.

(13) Despite subsection 8(12) the batch and expiry particulars required by paragraphs 8(4)(e) and 8(4)(f) may be embossed on a label attached to or appearing on the container or any primary pack containing a disinfectant.

(14) A common name referred to in paragraph 8(4)(a) must be:
(a) written immediately above, below or adjacent to the trade name of the disinfectant, or in the case of a disinfectant with no trade name, immediately below any statement required by any other regulation to be on the first line or lines of the main label; and
(b) must be in a font size that is similar for all parts of the common name.

(15) Where a disinfectant is demonstrated to pass as a hospital grade disinfectant under **Option A** of the prescribed test, the labelling must explicitly, clearly and in a way that highlights the requirement, indicate that the surface must be pre cleaned before disinfection for the process to be effective.

Schedule 1—The TGA disinfectant test

Note: This test method has been reproduced with the kind permission of the author and publisher from an original paper published in the "Australian Journal of Hospital Pharmacy", Vol 8, No 4; 1978 (152-155).

1 Principle

The method, as applied to Hospital Grade Disinfectants or Sanitisers, is essentially that given by Kelsey & Maurer (referred to in item 10(1)) for testing disinfectant performance. It is set out in a form suitable for attachment to a regulatory minimum standard for disinfectants. For wider application of the test refer to supplementary note A.

The disinfectant is tested at the dilution recommended by the manufacturer on the product label. The test consists of challenging the diluted disinfectant with bacterial inoculum, withdrawing a sample after a given time and culturing the sample in a suitable recovery medium. After this sampling, the mixture is again challenged by a second inoculum and after a second interval is again sampled for culturing. The sample is passed or failed according to the extent of growth shown in the two cultures sampled. The test may be performed with or without the addition of sterile yeast as an organic soil. (**Options B and A** respectively) or both, according to the use-situations advocated on the label of the product under test.

Table 1. Selection of test parameters for classes of disinfectant and antiseptic using the TGA Disinfectant Test.

Class of product	Organisms used in the test	Test option for resuspension of centrifuged organisms	Number of challenges	Inoculum density
Disinfectant - hospital grade: Sanitiser	*Ps. aeruginosa* *Pr. vulgaris* *E. coli* *S. aureus*	Option A ("clean" conditions)	2	$2x10^8$ - $2x10^9$
		Option B ("dirty" conditions")		
Disinfectant - household or commercial grade	*E. coli* *S. aureus*	Option C	1	$2x10^8$ - $2x10^9$

For Household Grade disinfectants, the first two organisms listed and the second challenge are omitted, while **Option C** (nutrient broth) is selected as the choice of simulated soil.

2 Media

All media must be contained in capped glass containers. Where media are stored, the containers must be sealed tightly or refrigerated.

2.1 Sterile Hard Water

2.1.1 Dissolve 0.304g anhydrous calcium chloride and 0.065g anhydrous magnesium chloride in glass-distilled water, and make up to one litre.

2.1.2 Dispense into glass containers and sterilize by autoclaving at 121° ±1° C for 15 minutes.

2.2 Yeast Suspension

2.2.1 Weigh 200g of moist compressed baker's yeast. Cream by the gradual addition of sterile hard water using a heavy glass rod for stirring. Decant the creamed portion into a flask, add more water to any lumpy residue remaining and repeat the creaming and decantation until no residue remains and 500ml of water has been used.

2.2.2 Shake the contents of the flask vigorously and strain through a 100-mesh sieve, breaking down any remaining lumps.

2.2.3 Add 500ml sterile hard water, shake vigorously and adjust the pH to 6.9-7.1 with 1N Sodium hydroxide.

2.2.4 Transfer 50ml, 100ml or 200ml of the yeast solution into screw-capped bottles.

2.2.5 Autoclave at 121° ±1° C for 15 minutes and allow the autoclave to cool without releasing pressure. Store cold but not freezing.

2.2.6 Dry two Petri dishes to constant weight. Into each, pipette 25ml of sterilised yeast suspension, and dry to constant weight at 100°C. Calculate the average solids content of the suspension.

2.2.7 Before use, pipette 25ml of the sterilised yeast suspension into a beaker. Determine the pH using the glass electrode, and determine the volume of 1N sodium hydroxide solution needed to adjust the pH to within the range 6.9 to 7.1.

2.2.8 Immediately before use, add to each bottle of sterilised yeast, a volume of sterile hard water and a volume of 1N sodium hydroxide calculated to adjust the concentration of dry yeast to 5.0% and the pH to within the range 6.9-7.1. Discard prepared yeast 3 months after preparation.

2.3 Medium for Growth of Test Organisms

2.3.1 Prepare a 10% w/v dextrose solution in distilled water, and sterilise by autoclaving at 121° ±1° C for 15 minutes. Cool to room temperature.

2.3.2 Prepare Wright and Mundy medium following the author's procedure (referred to in item 10(2)) or from a commercial product of the same composition (as referred to in item 11(b)) and sterilise by autoclaving at 121° ±1° C for 15 minutes. Cool to room temperature.

2.3.3 To each litre of Wright and Mundy medium prepared in item 2.3.2 add 10ml sterile dextrose solution prepared in item 2.3.1.

2.3.4 Aseptically dispense in either 10ml or 15ml amounts, as preferred.

2.3.5 This medium is referred to as ***Wright and Mundy dextrose medium***.

2.4 Recovery Medium

2.4.1 Prepare nutrient broth as follows or from a commercial product of the same composition (as referred to in item 11(b)):

Add the following to 970ml of water and dissolve by heating.

Beef Extract Powder	10g
Peptone	10g
Sodium Chloride	5g

Adjust the pH to 8.0-8.4 using 1N Sodium Hydroxide.

Boil for 10 minutes and filter. Cool.

2.4.2 To each litre of nutrient broth solution prepared in item 2.4.1 add 30g polysorbate 80 (as referred to in item 11(b)).

2.4.3 Adjust pH to 7.2-7.4 using 1N Sodium hydroxide.

2.4.4 Autoclave at 121° ±1° C for 15 minutes, and immediately shake well to disperse the polysorbate 80.

2.4.5 Dispense aseptically in 10ml amounts into sterile capped glass tubes.

3 Test Inoculum

3.1 Test Organisms

The following 4 organisms are to be used, except where prescribed.

Pseudomonas aeruginosa	NCTC 6749
Proteus vulgaris	NCTC 4635
Escherichia coli	NCTC 8196
Staphylococcus aureus	NCTC 4163

3.2 Preparation of Inoculum

3.2.1 Incubate the contents of an ampoule of freeze-dried culture overnight at 37° ± 1°C in Wright and Mundy dextrose medium.

3.2.2 Inoculate the incubated culture onto nutrient agar slopes in McCartney bottles. Store for up to 3 months at 4° ± 1°C.

3.2.3 At a suitable period before the test is to be conducted, sub-culture from an agar slope into 10ml or 15ml quantities of Wright and Mundy dextrose medium. Incubate at 37° ± 1°C for 24 ± 2 hours.

3.2.4 Sub-culture from the medium in item 3.2.3 into fresh medium, using an inoculating loop of 4mm in diameter. Incubate at 37° ± 1°C for 24 ± 2 hours.

3.2.5 Repeat item 3.2.4 daily. For the test procedure use only those cultures which have been sub-cultured at least 5 times, and not more than 14 times.

3.2.6 Filter test cultures of *P. aeruginosa* and *S. aureus* through sterile Whatmans No. 4 filter paper.

3.2.7 Centrifuge all test cultures until cells are compact, and remove supernatant with a Pasteur pipette.

3.2.8 Resuspend test organisms in the original volume of liquid (i.e. 10ml or 15ml), and shake for 1 minute with a few sterile glass beads.

3.2.8.1 For **Option A**, resuspend in sterile hard water.

3.2.8.2 For **Option B**, resuspend in a mixture of 4 parts yeast suspension (prepared as in item 2.2) to 6 parts sterile hard water.

3.2.8.3 For **Option C**, resuspend in nutrient broth (prepared as in items 2.4.1 and 2.4.3 and sterilised by autoclaving).

3.2.8.4 For **Option D**, resuspend in sterile hard water; dilute twice 1 + 9 in sterile hard water; then add 8ml of the last dilution to 2ml sheep serum previously inactivated at 56°C for 20 minutes and sterilised by filtration.

3.3 Enumeration of Inoculum

Immediately before testing, sample the resuspended inoculum and enumerate using 10-fold dilutions in quarter-strength Ringer's solution and the pour-plate technique. The number subsequently counted must represent not less than 2×10^8 or more than 2×10^9 organisms per millilitre (or 1×10^8 - 1×10^7 using **Option D**) or the test is considered invalid. Retain tube containing 10^{-7} dilution for use in controls (items 7.3 and 7.4).

4 Disinfectant Dilutions

Quantitatively dilute a sample of the disinfectant to the specified extent, using sterile hard water as diluent. Use not less than 10ml or 10g of sample for the first dilution, and not less than 1ml of any dilution to prepare subsequent dilutions. Make all dilutions in glass containers on the day of testing. The glass containers must be twice rinsed in glass-distilled water, and sterilised.

5 Temperature

Where air-conditioning does not maintain test solutions at 21° ± 1°C, hold the containers in which the test is to be carried out in a waterbath at this temperature.

6 Test Procedure

Perform the following test using each of the four test organisms (item 3.1) except where the Standard directs otherwise. It is not necessary to test with all organisms simultaneously.

6.1 Add 3ml of diluted disinfectant to a capped glass container.

6.2 Start a timing device. Immediately inoculate disinfectant with 1ml of culture (prepared in item 3.2) and mix by swirling.

6.3 At 8 minutes, subculture one drop (0.02ml ± 0.002ml) into each of 5 tubes containing recovery broth. To ensure delivery of 0.02ml into the first tube of recovery broth at exactly 8 minutes, it will be necessary to withdraw a suitable amount from the disinfectant test mix shortly beforehand. This must be immediately preceded by vortexing. Surplus sample must be returned to the test mix (refer to item 11(d)).

6.4 Except where prescribed, at 10 minutes, inoculate disinfectant with a further 1ml of culture, and mix by vortexing.

6.5 Except where prescribed, at 18 minutes, proceed as in item 6.3.

6.6 Mix the contents of all tubes of recovery broth by vortexing. Incubate at 37° ± 1°C for 48 ± 2 hours.

6.7 Examine for growth and record results.

6.8 For each test organism repeat steps 6.1-6.7 on each of 2 subsequent days, using a fresh disinfectant dilution and a freshly prepared bacterial suspension.

7 Controls

7.1 Recovery broth contamination

Incubate one uninoculated tube of recovery broth at 37° ± 1°C for 48 ± 2 hours and examine for growth. If growth occurs, the test is considered invalid due to contamination of the recovery broth.

7.2 Disinfectant contamination

To 1 tube of recovery broth, add 0.02ml of diluted disinfectant. Incubate at 37° ± 1°C for 48 ± 2 hours. If growth occurs, the test is considered invalid. Growth in item 7.2 but not item 7.1 indicates contamination of the disinfectant test solution.

7.3 Fertility Test

To 1 tube of recovery broth, add 1.0ml of the 10^{-7} dilution retained in item 3.3. Incubate at 37° ± 1°C for 48 ± 2 hours and examine for growth. If no growth occurs, the test is considered invalid.

7.4 Inactivator Efficacy

To 1 tube of recovery broth, add 0.02ml of diluted disinfectant and 1.0ml of the 10^{-7} dilution retained in item 3.3. Incubate at 37° ± 1°C for 48 ± 2 hours, and examine for growth. If no growth occurs, the test is considered invalid. Growth in item 7.3 but not in item 7.4 indicates inadequate inactivation of the disinfectant.

8 Procedure in case of invalid controls

When any control renders the test invalid, the test is to be repeated. Fresh recovery broth is to be used if growth occurred in control item 7.1 or if no growth occurred in controls items 7.3 or 7.4.

Should disinfectant contamination be indicated by control item 7.2 on both occasions, the disinfectant is considered to fail the test. Should inadequate inactivation of the disinfectant be indicated by control item 7.4 on both occasions, the test is considered invalid (refer to item 11(c)).

9 Results

The dilution test passes the test if there is no apparent growth in at least two out of the five recovery broths specified in item 6.3 and no apparent growth in at least two of the five recovery broths specified in item 6.5 on all three occasions, using all four organisms.

10 References

(1) Kelsey, J.C. and Maurer Isobel, M. Pharmaceutical Journal (UK) 213: 528-530, (1974).

(2) Wright Eleanore, S. and Mundy, R.A. Journal of Bacteriology 80: 279-280, (1960).

11 Supplementary Notes

(a) For investigational, developmental or comparative purposes, it will be useful to add a third challenge thus performing a true capacity test, and to test at dilutions above and below the prescribed dilution. In such cases, Kelsey & Maurer's recommendations regarding the timing and organisation of the test should be carefully consulted. Abbreviations of the test may be considered for the routine test of production batches.

(b) Wright & Mundy medium is commercially available as “Bacto Synthetic Broth”, A.O.A.C. Code No. 0352 (Difco Ltd.). The nutrient broth to be used is available as “Nutrient Broth - No. 2” (Oxoid Ltd.).

(c) Where inadequate inactivation is indicated, investigations should be conducted to find an effective inactivator. Refer Mackinnon, I.H.J. Hyg (London) 73: 189-195, (1974).

(d) The Oxford P-7000 sampler system with disposable plastic tips is recommended for the withdrawal of samples for subculturing

Schedule 2 – Physical Stability, Chemical Stability, Microbial Efficacy Testing and Shelf Life of Disinfectants

1 Principle

The physical stability, chemical stability and microbial efficacy of the product must be established on the final formulation and in the proposed packaging material. Laboratory batches may be used but they should appropriately reflect the scaled-up production process. A production batch of the product must be subjected to real-time stability testing for confirmation. Additional stability programmes are required where changes have taken place in the manufacturing procedures or the quality of the raw material.

2 General Requirements

All tests should be carried out by a GMP licensed laboratory or laboratory accredited to ISO/IEC 17025 or equivalent eg, NATA, TGA, US FDA, PIC/S, US EPA, NAMAS UK etc. Data sourced from non-accredited laboratories will only be accepted in relation to testing conducted using blood borne viruses, including HIV, Hepatitis B and C, Ebola and other haemorrhagic viruses.

Where international standards and test methods (CEN, AOAC, US EPA, ASTM) are referenced in testing, testing should be conducted against the current and relevant standard at the time the testing was conducted, and the edition number of the standard clearly stated within the testing results. Where testing has been conducted to a more recent standard than those set out below, the more recent standard will be acceptable.

Regardless of whether the product is used undiluted or diluted by the user to the Minimum Recommended Concentration (MRC), the product should be formulated at the lower extreme of ingredient specification, stored to expiration and then subjected to the microbial efficacy tests.

The product may be tested before the end of the shelf life to initially provide a full set of data for evaluation purposes if product stored to the end of the expiration period is not available. The data should be generated from more than one batch of product (preferably three batches). Testing at the end of the shelf life will then need to be performed according to the microbiological stability requirements specified below when product stored to the end of the expiration period becomes available. End of shelf life data should be generated from a minimum of two batches.

A common approach to developing a worst case product for testing is to use accelerated life testing to predict the final level of actives. These levels (with a safety factor) are then used in the formulation of a sample for efficacy testing. However, some products are unstable at elevated temperatures and may not be suitable for accelerated stability testing. In general, real time stability studies are preferred.

Data from all tests specified for each grade and level of disinfectant is not required for monitoring of stability (see table below for the appropriate tests to be used to generate stability data). Tests must be carried out at the pH, temperature and time (unless the stability studies are conducted under the accelerated conditions) recommended on the label for the use, or each level of use where there is more than one level.

Test methods must be validated by individual laboratories for each test method used in accordance with tests which have been validated or refereed at national or international level. This should involve validation of individual operators by performance of the specified test using a control or product that is known to pass the specified test at a given concentration as well as testing to determine the most appropriate neutraliser/inactivatorif necessary.

3 Physical Stability

Physical stability testing may include:
(a) appearance (eg. emulsion stability, clarity etc.)
(b) odour
(c) pH
(d) immediate container and product compatibility

The final formulation must pass at least one suitably sensitive test according to the appropriate evaluation guidelines for the level/grade of disinfectant (see table below) at the final end point with the levels of active(s) at the final predicted final level.

DISINFECTANT	APPROPRIATE TEST
Hospital Grade	Carrier test (with or without soil as appropriate
Household/Commercial Grade	TGA Test (Option C), or carrier test (with organic soil)

4 Chemical Stability

Chemical stability testing must comply with the following:
(a) active(s), to be determined by an assay that is valid for the active (eg. HPLC, GC, titration),
(b) active(s) to remain on or above 90% of the label claim at the end of the stated shelf life of the product,
(c) active(s) to be above the minimum level required to pass the appropriate TGA test(s) over the shelf life, and
(d) all chemical testing to be carried out on duplicate samples.

5 Microbial Efficacy

Hospital Grade Disinfectants

Bactericidal efficacy (excluding tuberculocidal) is the only mandatory requirement for a hospital grade disinfectant.

These disinfectants MUST pass Option B of the TGA Disinfectant Test under dirty conditions. This is a semi-quantitative suspension test. Testing in accordance with the dirty conditions option of EN 13727:2012 +A2:2015[1] will also be accepted. Other suspension tests may be acceptable if modified to include 5% organic soil and water of minimum hardness 320-400ppm.

If the disinfectant is clearly labelled for use on a pre-cleaned surface, Option A of the TGA Disinfectant Test may be used. Under these circumstances, the clean conditions option of EN 13727:2012 +A2:2015 will also be accepted as an evaluation test. Other suspension tests may be acceptable under clean conditions provided hard water (320-400ppm) is used.

If specific label claims are made for vegetative bacterial species other than those covered by the required test organisms, the testing above must be conducted using these additional organisms. Specific testing as described below must be conducted when label claims are made for activity against mycobacteria and spore-forming organisms.

These disinfectants MUST also pass a bactericidal carrier test. AOAC[2][3] methodology (60 carriers per organism) or equivalent method, such as ASTM E2197-11[4] or ASTM E2111-12[5] may be used. Testing conducted in accordance with EN 14561:2006[6] or EN 13697:2015[7] will be accepted if modified to use 60 carriers per test organism. If the AOAC Use Dilution Test is chosen, the disinfectant passes when there is no growth in 59 out of 60 carriers per organism. If the Hard Surface Carrier Test is used, the criteria for pass or fail are described in the test method. If 10 carriers are used for additional claims, no carriers may show growth. If the ASTM or other methods are used, the test organisms and test criteria as described in the AOAC Hard Surface Carrier Test apply.

[1] European Standard EN 13727:2012 +A2:2015 *Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)*

[2] *Official Methods of Analysis of the AOAC International*, current edition, Use-Dilution Method 955.15 and 964.02

[3] *Official Methods of Analysis of the AOAC International*, current edition, Hard Surface Carrier Test Methods

[4] ASTM E2197-11 *Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides*

[5] ASTM E2111-12 *Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal and Sporicidal Potencies of Liquid Chemicals*

[6] European Standard EN 14561:2006 *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

[7] European Standard EN 13697:2015 *Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)*

If additional claims regarding organisms not included in the original test are to be made (eg "Kills E coli O157), the extra organism(s) can be tested using 10 carriers rather than 60. Soil should be included at a minimum of 5% blood serum and inorganic soil such as hard water at a minimum of 340ppm.

If any specific biocidal claims are made (i.e., virucidal, fungicidal, tuberculocidal, sporicidal, or other biocidal activity), the disinfectant must pass suitable tests with added soil (5% organic soil and inorganic soil such as hard water) for that particular claim. This requirement applies regardless of whether Option A or Option B of the TGA Test has been used. All tests should be carried out using the exposure time, temperature and pH specified on the label.

For a fungicidal claim, any test of reasonable scientifically-based, peer reviewed methodology will be considered, although carrier test methodology is preferred. Acceptable tests include the AOAC Use Dilution Test, which can be modified for fungi, with 10 carriers for each of two batches of product, and acceptance criteria of all fungal spores on all carriers killed, the AOAC Fungicidal Test[8], which can be modified for a carrier test, and the ASTM E2197-11 test methodology, with acceptance criteria as for the modified AOAC Use Dilution Test. Tests conducted in accordance with EN 13624:2013[9] or EN 13697:2015 will also be accepted.

For a general virucidal claim, not including blood borne viruses such as HIV, HBV, HCV, Ebola etc., the disinfectant MUST pass tests with added soil, using Poliovirus/Parvovirus and Herpes simplex as the test viruses.

The tests may be suspension tests but carrier tests are preferred. Methods that may be used as a basis are the AOAC Use Dilution Test modified for viruses and ASTM E2197-11. One surface is required to be tested for each of two batches of product. Guidance on carrier test methodology is provided in ASTM E 1053-11[10]. Guidance on suspension test methodology is provided in ASTM E 1052-11[11]: *Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension.* If a suspension test is used, the methodology of EN 14476:2013[12] is acceptable, if the test is conducted under dirty conditions and if Herpes simplex is used in addition to the organisms required by the standard.

NOTE: The World Health Organisation (WHO) is conducting a global campaign aimed at the eradication of Polio. As a result, there will be restrictions on the use of Poliovirus (both wild and vaccine strains), in the laboratory. For this reason, other viruses may be accepted for demonstration of virucidal efficacy. Possible alternatives include Hepatitis A or Feline

[8] *Official Methods of Analysis of the AOAC International*, current edition, Fungicidal Activity of Disinfectants Method 955.17

[9] European Standard EN 13624:2013 *Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – Test method and requirements (phase 2, step 1)*

[10] ASTM E 1053-11 *Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces*

[11] ASTM E 1052-11 *Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension*

[12] European Standard EN 14476:2013 *Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)*

Calicivirus, however, any company choosing a virus other than Poliovirus/Parvovirus for virucidal testing should justify the use of an alternative virus - the justification should include evidence that the virus chosen is of equivalent resistance in in-vitro testing.

Viral recovery systems that may be used include tissue culture, embryonated egg and animal inoculation.

Tests on the designated prototype viruses should be performed in quadruplicate against a recoverable viral titre of at least 4-$\log_{10}$, which must be recoverable from the test surface or suspension, and should show complete viral inactivation. If cytotoxicity is apparent, a 3-$\log_{10}$ reduction must be demonstrated beyond the cytotoxic level and there should be complete viral inactivation. Cytotoxicity is more easily overcome in suspension tests, for which there should be a 4-$\log_{10}$ reduction with complete viral inactivation. Suitable controls should be employed, which include

- cytotoxicity controls,
- disinfectant neutralization controls,
- quantitative viability control,
- cell control, and
- carrier wash-off control.

If a label claim against HIV, Hepatitis B (HBV), Hepatitis C (HCV) or other specific virus is made, separate data must be provided, in addition to the above. Suspension tests may be used for additional specific viral claims, but the recoverable viral challenge should reflect the titre found in the clinical situation. Complete viral inactivation is preferred, with a minimum 4-log reduction of specific viruses. For HIV, the method should be based on the principles described above. The use of a surrogate virus for HIV claims is not permitted.

For viruses that cannot be cultured, surrogate viruses may be used. For HBV, tests with a surrogate organism such as Duck Hepatitis B Virus (DHBV) are acceptable. The electron microscope viral disruption and antigenicity tests are NOT acceptable, as they are not reliable indicators of HBV infectivity. A suitable surrogate for HCV may be Bovine Viral Diarrhoeal Virus (BVDV). Tests for HIV and HCV MUST be conducted against cell-associated virus – a suspension test may be used if necessary. Organic soil for tests against HIV and surrogates for HBV and HCV and Ebola MUST be a minimum of 50% whole blood. Suitable references for test methods are Murray (1991)[13], Druce (1995)[14], and Lavelle (1987)[15].

With regard to testing against HIV, there can be difficulties associated with testing using cell-associated virus. Non-cell associated virus can be used for HIV testing of hospital or household grade disinfectants not intended for use on medical devices if:

- a carrier test is used instead of a suspension test;
- the minimum level of organic soil used in the test is 50% whole blood; and
- the product is clearly labelled for use on a pre-cleaned surface.

[13] Murray SM, JS Freiman, K. Vickery, D.Lim, YE Cossart, RK Whiteley "Duck Hepatitis B Virus: a model to assess efficacy of disinfectants against hepadnavirus activity". *Epidemiol Infect* (1991) 106, 435 – 443

[14] Druce JD, D Jardine, SA Locarnini, CJ Birch "Susceptibility of HIV to inactivation by disinfectants and ultraviolet light" *Journal of Hospital Infection* (1995) 30 pp

[15] Lavelle George C, "Virucidal activity of Disinfectants: Predicting and Assessing Product Efficacy" *Chemical Times and Trends*, January 1987 45-50

There are a number of other viruses which cannot be cultured which may be the subject of label claims. These include Norwalk virus and Norovirus. There are also viruses such as SARS associated coronavirus, which can be cultured but may not be suitable for use in test laboratories due to biosecurity issues. Feline calicivirus has been accepted as a surrogate to justify claims against Norwalk and Noroviruses. Human coronavirus is suggested as a surrogate for SARS associated coronavirus if the SARS virus cannot be used.

If virucidal testing is limited to lipid/enveloped viruses, such as Herpes simplex virus, a label claim for general virucidal activity will not be permitted. The label must reflect the specific viruses used for the limited testing.

For a tuberculocidal claim, results from a quantitative carrier test should be provided. A variety of organisms may be used, such as

M bovis	(BCG)
M tuberculosis	H37RV
M terrae	ATCC 15755

NOTE: *M smegmatis* is NOT acceptable as this organism is comparatively easy to kill and its resistance patterns are substantially different from *M bovis* etc.

The acceptance criterion is a 6-$\log_{10}$ reduction in test organisms. If the carrier test used is not quantitative (eg the AOAC *Test for Tuberculocidal Activity of Disinfectants*[16]), a suspension test may be used to demonstrate a 6-log reduction.

Suitable tuberculocidal tests that may be modified in line with points raised above include:

- the AOAC *Test for Tuberculocidal Activity of Disinfectants* (with the exception of the in-vitro screening test using *M smegmatis*);
- the EPA *Quantitative Tuberculocidal Activity Test*[17]
- ASTM E2111-12;
- ASTM E2197-17e1;
- the Ascenzi test[18]; and
- EN 14348:2005[19]

For a sporicidal claim, a carrier test or a suspension test may be used. The results should show a 6-$\log_{10}$ reduction in spores. However, if the AOAC Sporicidal Test[20] is used, growth is allowed from two carriers or less. Other carrier tests that may be suitable are those performed

[16] *Official Methods of Analysis of the AOAC International*, current edition, Tuberculocidal Activity of Disinfectants Method 965.12

[17] US EPA *Standard Operating Procedure for Quantitative Suspension Test Method for Determining Tuberculocidal Efficacy of Disinfectants Against Mycobacterium bovis (BCG)*, SOP Number: MB-16-01, 2009

[18] Ascenzi JM, RJ Ezzell, TM Wendt, "A More Accurate Method for Measurement of Tuberculocidal Activity of Disinfectants" *Applied and Environmental Microbiology*, Sept 1987 p2189-2192

[19] European Standard EN 14348:2005 *Chemical disinfectants and Antiseptics – Quantitative Suspension Test for the Evaluation of Mycobactericidal Activity of Chemical Disinfectants in the Medical Area including Instrument Disinfectants – test methods and requirements (phase 2, step 1)*

[20] *Official Methods of Analysis of the AOAC International*, current edition, Sporicidal Activity of Disinfectants Test – Method II, Method 966.04

by the Hospital Infection Research Laboratory at Dudley Road Hospital, Birmingham, UK[21], and tests conducted in accordance with ASTM E2197-17e1, with acceptance criteria as for the AOAC Sporicidal Test. The methodology of EN 13704:2018[22] will be accepted, if the test is modified to show a 6-$\log_{10}$ reduction in spores.

Suitable test organisms include:

Clostridium sporogenes	ATCC 3584
Bacillus subtilis	ATCC 19659 or NCTC 10073

Label claims against *Clostridium difficile* can only be made if the methodology uses spores. The claim cannot be made if a vegetative form of *C difficile* is used.

Hospital grade cloth wipes

The following tests are intended to apply to products making claims of surface disinfection. They are not intended to apply to products claiming activity solely within the cloth.

A hospital grade disinfectant wipe is required to:

1.) Pass a bactericidal suspension tests, such as the TGA Test (Option B for dirty conditions, Option A for clean conditions), or EN 13727:2012 +A2:2015. The suspension test chosen should be conducted on the product after extraction from the wipe. Testing in accordance with the European Standard EN 16615:2015[27] will also be accepted.

2.) Alternatively, a modified AOAC Germicidal Spray Test[23] may be used, with 60 carriers, tested by wiping the surface of the carriers with the saturated wipe and subculturing the carriers after the specified contact time. One wipe should be used for a minimum of 10 carriers. The performance criteria should be no growth from 59/60 carriers.

3.) If a suspension test is used, the product must pass a simulated in-use test showing that the efficacy of the disinfectant is not reduced when combined with a cloth. Organic soil at a minimum of 5% blood serum must be included for products used under dirty conditions. The design of the test should be based on a carrier/surface test and could involve wiping the cloth over a carrier/surface and culturing both the carrier and the liquid that has been expressed from the used cloth. Alternatively, the entire cloth could be cultured.

4.) Any test of reasonable design employing these principles may be acceptable. At least 60 carriers/surfaces should be used per organism tested with 59/60 carriers showing no growth. The US EPA document "Product Performance Test Guidelines[24]" provides guidance on acceptable test methodology.

[21] "Sporicidal Activity of Glutaraldehyde and Hypochlorites" *Journal of Hospital Infection*, (1980) 1 63-75

[22] European Standard EN 13704:2018 *Chemical disinfectants - Quantitative Suspension Test for the Evaluation of Sporicidal Activity of Chemical Disinfectants used in Food, Industrial, Domestic and Institutional areas - test method and requirements (phase 2, step 1)*

[23] European Standard EN 1276:2009 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1*

[24] United States Environmental Protection Agency "Product Performance Test Guidelines" OCSPP 810.2200: *Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations*, 2012

5.) If specific biocidal claims are made, all claims should be supported with data from a suspension or carrier test, with added soil as appropriate. These tests should be carried out according to the requirements of hospital grade disinfectants as detailed above. The simulated in-use test can be carried out using the organism from the most stringent claim. This is in addition to verifying the most stringent claim with a carrier or suspension test.
6.) Where a cloth wipe is reusable, the wipe must pass a simulated in-use test after the product has been subjected to a re-use protocol. Any reasonably designed test will be considered – a suggested method would include challenging the cloth or towelette by wiping it on a variety of surfaces. These surfaces should have been subject to periodic contamination with a microbiological bioburden at a concentration of 10^6 CFU/5mL use solution. The cloth should be allowed to dry between uses. At the end of the use period, the product should be subjected to a simulated in-use test as described in clause 3 above.

Hospital grade cloth wipes and sponges where the ingredient that is active cannot be expressed

Any reasonably designed test will be considered – a suggested method would include challenging the sponge by wiping it on a variety of surfaces. These surfaces should have been subject to periodic contamination with a microbiological bioburden. The sponge should be allowed to dry between uses. At the end of the use period, the product should be subjected to a simulated in-use test as described in clause 3 of "Hospital grade cloth wipes". If claims against specific bacteria are made, then these organisms should be included in the test. Testing in accordance with EN 16615:2015[25] will also be accepted.

Hospital grade surface sprays

A hospital grade surface spray disinfectant is required to:

1.) Pass a bactericidal carrier test such as the AOAC Germicidal Spray Test. Testing in accordance with EN 14561:2006 or EN 13697:2015 will be accepted (test to be chosen depends on intended use – for hospital grade disinfectants, EN 14561 is the most appropriate). Sixty carriers per organism should be used, plus 10 carriers for each additional bactericidal claim. The performance criteria should be no growth from 59/60 carriers.
2.) Pass the tests specified in clause 1 with added organic and inorganic soil (if the product is for dilution). Organic soil should be a minimum of 5% blood serum and inorganic soil should be hard water (minimum hardness 340ppm). For products intended for use on pre-cleaned surfaces, organic soil need not be included. A surface spray should be tested against *Salmonella enterica* serotype *choleraesuis* (*Salmonella choleraesuis*), *Staphylococcus aureus* and *Pseudomonas aeruginosa* if the AOAC Germicidal Spray Test is used. If other tests are chosen, it is expected that organisms similar to these would be used.
3.) Pass carrier tests as described in previous clauses, if specific biocidal activities are claimed. Inorganic and organic soil should be included.

[25] European Standard EN 16615:2015 *Chemical disinfectants and antiseptics. Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test). Test method and requirements (phase 2, step 2)*

Commercial/household grade disinfectants

Commercial/household grade disinfectants must pass Option C of the TGA Test, or a test conducted in accordance with EN 1276:2009[26], OR

1) Pass a suitable bactericidal carrier test, using AOAC methodology (60 carriers per organism), EN 13727:2012 +A2:2015 or EN 13697:2015[27] (using 60 carries per test organism). Organic soil is not necessary but inorganic soil such as hard water of minimum hardness 340ppm should be included. 10 carriers should be used for each additional organism.
2) Pass tests as for hospital grade disinfectants where specific biocidal activities are claimed. Inorganic soil should be included.

Commercial/household grade disinfectants cloth wipes

The following tests are intended to apply to products making claims of surface disinfection. They are not intended to apply to products claiming activity solely within the cloth.

A commercial/household grade disinfectant wipe is required to:

1) Pass the TGA Test Option C or testing in accordance with EN 13727:2012 +A2:2015 or EN 1276:2009[28]. The test should be conducted on the product after extraction from the wipe. Organic soil is not necessary but inorganic soil such as hard water of minimum hardness 340ppm should be included. Alternatively, a modified AOAC Germicidal Spray Test as described for hospital grade disinfectants may be used. Testing in accordance with EN 16615 will also be accepted.
2) If a suspension test is used, the product must also pass a simulated in-use test showing that the efficacy of the disinfectant is not reduced when combined with a cloth. Organic soil need not be included unless specific instructions for use on soiled surfaces are included on the label. The test method should be based on that described in clause 3 of "Hospital grade cloth wipes". At least 60 carriers/surfaces should be used per organism tested, with 59/60 carriers showing no growth.
3) If specific biocidal claims are made, all claims should be supported with data from a suitable suspension or carrier test. These tests should be carried out as described for other household/commercial grade disinfectants. The simulated in-use test can be carried out using the organism from the most stringent claim. This is in addition to verifying the most stringent claim with a carrier or suspension test.
4) Where a cloth wipe is reusable, the wipe must pass a simulated in-use test after the product has been subjected to a re-use protocol. Any reasonably designed test will be considered – a suggested method would include challenging the cloth or towelette by wiping it on a variety of surfaces. These surfaces should have been subject to periodic

[26] European Standard EN 13697:2015 *Chemical disinfectants and Antiseptics – Quantitative Non-porous Surface Test for the Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants used in Food, Industrial, Domestic and Institutional Areas – test method and requirements without mechanical action (phase 2, step 2)*

[27] *Official Methods of Analysis of the AOAC International*, current edition, Germicidal Spray Products as Disinfectants, Method 961.02

[28] European Standard EN 1276:2009 *Chemical disinfectants and antiseptics . Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)*

contamination with a microbiological bioburden at a concentration of 10^6 CFU/5mL use solution. The cloth should be allowed to dry between uses. At the end of the use period, the product should be subjected to a simulated in-use test as described in clause 3 of "Hospital grade cloth wipes".

Commercial/household grade cloth wipes and sponges where the ingredient that is active cannot be expressed

Any reasonably designed test will be considered – a suggested method would include challenging the sponge by wiping it on a variety of surfaces. These surfaces should have been subject to periodic contamination with a microbiological bioburden. The sponge should be allowed to dry between uses. At the end of the use period, the product should be subjected to a simulated in-use test as described above. If claims against specific bacteria are made, then these organisms should be included in the test. Testing in accordance with EN 16615:2015 will also be accepted.

Commercial/household grade surface sprays

A commercial/household grade surface spray disinfectant is required to:

1) Pass a bactericidal carrier test such as the AOAC Germicidal Spray Test. Testing in accordance with EN 14561:2006 or EN 13697:2015 will be accepted (test to be chosen depends on intended use). Sixty carriers per organism should be used, plus 10 carriers for each additional bactericidal claim. The performance criteria should be no growth from 59/60 carriers.
2) Pass the tests specified in clause 1 with added inorganic soil, if intended as a surface spray that is diluted before use. A surface spray should be tested against *Salmonella enterica* serotype *choleraesuis* (*Salmonella choleraesuis*) *and Staphylococcus aureus* if the AOAC Germicidal Spray Test is used. If other tests are chosen, it is expected that organisms similar to these would be used.
3) Pass carrier tests as described in previous clauses, if specific biocidal activities are claimed. Inorganic soil should be included.

6 Stability Testing Frequency

Accelerated Studies - suggested testing intervals are:

0, 3, 6 and 12 months but other time points eg. 1, 2, or 5 months may also be used and may be necessary for adequate accelerated studies. The minimum active concentration level from which the shelf life is predicted from accelerated data should be no lower than the minimum active concentration required to pass the appropriate microbial test.

Real Time Studies - Testing at initial and annual intervals should be sufficient. However, it is not necessary to have completed these testing programs before launching the product. Samples from production should undergo real time testing. These samples should be monitored over the shelf life of the product as proposed by the sponsor.

7 Packs for Stability Testing

Stability testing should be carried out on product stored in the proposed packaging material and in the case of real time testing this requirement is mandatory.

8 Prediction of Shelf Life

Shelf life may be predicted from accelerated data only if the accuracy and reproducibility of the results is adequate to support the extrapolation. All data must be fully defensible.

Extrapolation at various times and temperatures may be determined according to the following general rules:

Elevated Temp[(a)] above storage conditions[(b)]	Time Period	Possible Shelf Life Prediction
+10◦C	3 months	1 year
+15◦C	3 months	18 months
+10◦C	6 months	2 years
+15◦C	6 months	3 years
+10◦C	9 months	3 years

(a) incubator temperatures must be monitored and logged

(b) storage conditions for Australia are considered to be the temperatures of 25 - 30°C. The reference temperature used for stability testing will be that on the label.

Alternative predictive models/rules for extrapolation can be used however after proper scientific validation.

At least four real time data points, including the initial and three months, should be evaluated using acceptable statistical methods to justify the extrapolation.

The predicted value of the final concentration of the disinfectant active should not fall below the 90% limit of the label claim at the end of the extrapolated shelf life.

The stability programme should collect real time data from a production batch stored at the recommended storage condition. This should be used to confirm the extrapolated shelf life. The TGA should be advised if the product falls outside specification with appropriate action commensurate with public safety negotiated and agreed.

If there are minor changes to excipients, product stability should be confirmed, together with a single microbial efficacy test as for the final determination of shelf life.

Schedule 3—Acceptable Common Names

Descriptive Name	**Common Names**
Hospital grade disinfectant (see Surface spray below if primarily for use as a spray)	Disinfectant - hospital grade Hospital Grade Disinfectant
Household/Commercial grade disinfectant (see Surface spray below if primarily for use as a spray)	Disinfectant - household grade, or Disinfectant - commercial grade, or Household Grade Disinfectant, or Commercial Grade Disinfectant
Surface spray disinfectant	Surface spray disinfectant - hospital grade, or Surface spray disinfectant - household grade, or Surface spray disinfectant - commercial grade
Disinfectant Wipes	Disinfectant wipes – hospital grade, or Disinfectant wipes – household grade, or Disinfectant wipes – commercial grade
Antibacterial clothes preparation	Antibacterial (together with a word or words indicating the nature of the product)
Sanitary fluid	Sanitary fluid
Sanitary powder	Sanitary powder
Sanitiser	Sanitiser, or Sanitising Solution, or Antibacterial (together with a word or words indicating the nature of the product)