



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Therapeutic Goods Order Number 54

**STANDARD FOR HOUSEHOLD/COMMERCIAL AND HOSPITAL GRADE
DISINFECTANTS**

I, (National Manager of TGA), delegate of the Minister of State for Health and Ageing, for the purposes of the exercise of the Minister's powers under section 10 of the *Therapeutic Goods Act 1989* and acting under subsection 10(1), hereby **DETERMINE** that the matters specified in this Order shall constitute a standard for composition, packaging, labelling and performance of household/commercial and hospital grade disinfectants.

For the purpose of this Order, Schedules 1, 2 and 3 to this Order shall be deemed to be part of the standard.

1. Application

- (a) This order applies to all household/commercial and hospital grade disinfectants except -
- i) antiseptics and skin disinfectants;
 - ii) antibiotics;
 - iii) a disinfectant that is represented to be suitable for antifungal use only;
 - iv) 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 which is registered for the disinfectant;
 - v) a disinfectant or sanitiser that is represented to be suitable for the treatment of water only.
- (b) For the purpose of this Order the term disinfectant includes the grades of disinfectant specified as household/commercial grade and hospital grade.

2. Interpretation

Unless otherwise specified, the definitions in the *Therapeutic Goods Act 1989* and Therapeutic Goods Regulations will apply.

In this order unless the contrary intention appears:

"active ingredient" means a therapeutically active component in the final formulation of a therapeutic good;

“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" means a substance:

- (a) that is recommended by its manufacturer for dermal application; or application to the mucous membranes of a person or animal to kill micro-organisms; or to prevent the growth of micro-organisms to a level that may cause clinical infection; and
- (b) that is not represented to be suitable for internal use;

"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 Regulation 2 of the Regulations

[NOTE the definition as at the date of this order is as follows:
Australian Approved Names List means the document entitled Australian Approved Names for Therapeutic Substances, as in force from time to time, published by the Therapeutic Goods Administration.

Note 1 Australian Approved Names List includes:

- a. Australian Approved Names – Chemicals List; and
- b. Australian Approved Names – Biological Lists; and
- c. the Herbal Substances AAN List.

Note 2 Australian Approved Names List may be published as part of a larger document, for example, the document entitled TGA Approved Terminology for Medicines.

Note 3 The TGA Approved Terminology for Medicines document includes a subsection of Australian Device Names (ADN's) which are also Australian Approved Names]

"batch" means a quantity of product that is uniform in composition, method of manufacture and probability of chemical or microbial contamination and is made in one cycle of manufacture;

"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. Note: 'biocidal' is the adjective of biocide;

"common name" in relation to a substance listed in Column 1 of Schedule 2 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);

"container" means the ampoule, blister pack, bottle, can, cover, drum, sachet, strip pack, syringe, tube, vessel, vial, wrapper or other similar article that immediately covers the disinfectant;

"disinfectant" means a substance:

- (a) that is recommended by its manufacturer for application to an inanimate object to kill a range of micro-organisms; and
- (b) that is not represented by the manufacturer to be suitable for internal use;

NOTE: See Clause 1(a) for goods excluded from the Order.

"fungicide" means a chemical agent that kills fungi or spores of fungi.

Note: "fungicidal" is the adjective of fungicide;

"Excipient" means any component of a finished dosage form other than an active ingredient;

"Expiry date" or **"Use by date"** means the date (month and year) after which the goods should not be used, being a date not more than five years after the date of manufacture;

"hospital grade disinfectant" means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces, and purposes not involving medical devices or surfaces likely to come into contact with broken skin:

- (a) in premises used for:
 - (i) the investigation or treatment of a disease, ailment or injury; or
 - (ii) procedures that are carried out involving the penetration of the human skin; or
 - (iii) manufacture of therapeutic goods ie cleanrooms;
- (b) in connection with:
 - (i) the business of beauty therapy or hairdressing; or
 - (ii) the practice of podiatry;

but does not include:

- (a) instrument grade disinfectants; or
- (b) sterilant; or
- (c) an antibacterial clothes preparation; or
- (d) a sanitary fluid; or
- (e) a sanitary powder; or
- (f) a sanitiser;

"household/commercial grade disinfectant" means a disinfectant that is suitable for general purpose disinfection of building or fitting surfaces, and for other purposes, in premises or involving procedures other than those specified for a hospital grade disinfectant, but is not:

- (a) an antibacterial clothes preparation; or
- (b) a sanitary fluid; or

- (c) a sanitary powder; or
- (d) a sanitiser;

"hygienic hand rub" has the same meaning as skin disinfectant;

"hygienic hand wash" has the same meaning as skin disinfectant;

"label" means a display of printed information:

- (a) on or attached to the goods;
- (b) on or attached to a container or primary pack in which the goods are supplied; or
- (c) supplied with such a container or pack

"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 product name or, where there is no product name, the name of the goods is more or most conspicuously shown; or
- (b) where the product name or, where there is no product 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;

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

- (a) (i) where the manufacturer or sponsor has a registered name, that registered name; or
(ii) 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
- (b) (i) 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
(ii) 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;

"new chemical entity" means an active ingredient of a sterilant or disinfectant which is not included as an active ingredient in a sterilant or disinfectant product currently entered in the Australian Register of Therapeutic Goods (ARTG), or an excipient of a sterilant or disinfectant which is not included in either the Australian Inventory of Chemical Substances (AICS) or the ARTG.

"pass" means to meet or exceed the minimum requirement specified in Clause 3(4) in relation to the prescribed test or where other tests are involved for other biocidal activities, the criteria specified in or for those tests.

"Poisons Standard" means the current edition of the Standard for the uniform scheduling for drugs and poisons published by the Australian Health Ministers' Advisory Council

"prescribed test" means the "TGA Disinfectant Test" described in Schedule 1 of this Order;

"primary pack" means the complete pack in which the disinfectant and its container are to be sold to consumers;

"sanitary fluid" or **"sanitary powder"** 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;

"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 1: 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 for so long as they do not claim to be a disinfectant.

Note 2: Industrial food sanitisers which are exclusively used for cleaning food contact surfaces in industrial situations and which claim to reduce micro-organisms other than viruses to a sanitary level and are subject to user specifications, or a recognised International, Australian or industry standard, will not be regarded as a disinfectant so long as 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" means a chemical agent that:

- (a) kills bacterial spores; and
- (b) has the potential to act as a sterilising agent after prolonged contact times with an inanimate object;

Note: "sporicidal" is the adjective of sporicide.

"sterilant" means a chemical agent which is used to sterilise critical medical devices. A sterilant kills all micro-organisms with the result that the sterility assurance level of a microbial survivor is less than 10^{-6} ;

NOTE: sterilant gases are not within the scope of this Order. See Clause 1(a).

"suitable" means, when used in respect of a test to be passed, that the test is consistent with the recommendations and requirements in the document titled, "Guidelines for the Evaluation of Sterilants and Disinfectants" as amended from time to time and published by the TGA..

"**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;

"**tuberculocide**" means a chemical agent that kills *Mycobacterium tuberculosis* and related acid-fast bacteria.

Note: "tuberculocidal" is the adjective of tuberculocide;

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

Note: "virucidal" is the adjective of virucide;

3. Standards for performance of Disinfectants and Sterilants

- (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 shall 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; and
 - (ii) pass a suitable bactericidal carrier test; and
 - (iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests 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; and
 - (ii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests 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, 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 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.

- (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 shall 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**
 - (ii) pass a suitable bactericidal carrier test;and
 - (iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests 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; and
 - (ii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests 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 on 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, when the test is carried out on the product after extraction from the wipe
 - (ii) pass a suitable (single or multiple) simulated in-use test
 - (iii) pass suitable sporicidal, fungicidal, tuberculocidal, virucidal or other biocidal tests only where a claim has been 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
- (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 lowest concentration of disinfectant recommended on the label (where the product is to be diluted before use) for that use and at the end of the shelf life of the disinfectant prepared for that use.
- (4) Notwithstanding the requirements of clauses 3(1) and 3(2) a disinfectant shall 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) Microbial stability testing must be conducted on the final formulation, which must pass the most stringent suitable test in accordance with Clause 3 for the grade of disinfectant at the end of the real time shelf life. Microbial stability studies must be repeated to confirm shelf life whenever there are changes to the manufacturing process, the formula or the packaging and when the shelf life is to be extended.
- (6) In relation to the microbial quality of disinfectants, ideally, there should be no microbial contamination. However, unless products are intended to be sterile, it is likely that some contamination may be present. This should be kept to a minimum and must not contain pathogenic organisms or inappropriate organisms (ie vegetative bacteria in a product marketed as bactericidal).

4. Standards for Packaging and Labelling of Disinfectants and Sterilants

Packaging

- (1) A disinfectant shall be enclosed in a container.
- (2) The container shall 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 shall comply with the Poisons Standard and/or the Australian Dangerous Goods Code as amended from time to time.

Labelling

- (3) Labelling for all goods covered by this Order shall comply with the requirements of the Poisons Standard, as amended from time to time, except that where there is a conflict the requirement specified in this Order shall have precedence. Goods for non-domestic/Industrial purposes shall comply with the Poisons Standard or the National Occupational Health and Safety Commission's National Code of Practice for the labelling of workplace substances.
- (4) The container and any primary pack containing a disinfectant shall be labelled with the following particulars:
 - (a) a *common name* of the disinfectant as listed in Column 2 to Schedule 2 to this Order.
 - (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 shall 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 ", "the Upper Case (Capital) letter B surrounded by a circle" 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 bar code at this time.

- (g) the recommended storage conditions for the disinfectant.
Note: This requirement will take effect at the next label print run.
- (h) the name and address of the manufacturer or sponsor of the disinfectant;
- (i) 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 clauses 4(5) and 4(6) the words "Do not mix with detergents or other chemicals";
 - (iii) subject to clause 4(8), a statement of the dilution or dilutions of the disinfectant in water or other diluent to be employed or the words "Use undiluted"; and
 - (i) in the case of a disinfectant requiring preparation before use, instructions for correct preparation, use and storage conditions of the preparation should be supplied.

Specifications, Modifications and Exceptions

- (5) The words required by Clause 4(4)(i) (i) will, in the case of a hospital grade disinfectant, indicate that it is not intended to be used on medical devices.
- (6) The words required by Clause 4(4)(i) (ii) may be followed by the word "except", the name of a specific substance or product and the words "as directed below".
- (7) Clauses 4(4)(i) (ii) and (iii) do not apply in the case of a surface spray disinfectant.
- (8) For a liquid disinfectant, the statement of dilution (if applicable), referred to in clause 4(4)(i) (iii) to be employed shall 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.
- (9) In the case of a hospital grade disinfectant the statement of dilution referred to in clause 4(4)(i)(iii) shall not contain directions for the preparation of a dilution of the disinfectant from another such dilution.
- (10) The particulars referred to in clause 4(4)(a), (b), (c) and (d) shall be written on the main label.
- (11) The particulars referred to in clause 4(4) shall 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.
- (12) Despite subclause 4(11) the batch and expiry particulars required by paragraphs 4(4)(e) and 4(4)(f) may be embossed on a label attached to or appearing on the container or any primary pack containing a disinfectant.
- (13) A common name referred to in clause 4(4)(a) shall 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) shall be in a font size that is similar for all parts of the common name.

- (14) Where a disinfectant is demonstrated to pass as a hospital grade disinfectant under Option A of the prescribed test, the labelling shall 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.

5. Toxicity

- (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 disinfectant and that disinfectant contains an **active ingredient** that is a new chemical entity, a minimum data set of information on toxicity of the active ingredient, as represented by results from a suitable test, shall apply as follows:

- (a) studies on acute toxicity, to include
- (i) oral LD₅₀
 - (ii) inhalational LC₅₀
 - (iii) skin irritation
 - (iv) eye irritation
 - (v) skin sensitisation
 - (vi) dermal LD₅₀ is recommended, but is not mandatory.
- (b) repeat dose toxicity, consisting of an oral study up to 90 days, with a 28 day study as a minimum. The study protocol must include comprehensive histological, clinical biochemistry and haematological evaluation.
- (c) genotoxicity. As a minimum, test results are required for
- (i) point mutations in bacteria; and
 - (ii) chromosome damage in mammalian cells (*in vivo* or *in vitro*)
- (d) A chronic/carcinogenicity study is required where genotoxicity studies yield clear or equivocal positive findings.
- (e) Occupational health monitoring studies.
- (f) Teratogenicity studies in at least one of the following species are recommended, but are not mandatory:
- (i) rat
 - (ii) rabbit
 - (iii) studies in both species is preferable

- (2) 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 disinfectant and that disinfectant contains an **excipient** that is a new chemical entity, a minimum data set of information on toxicity of the excipient, as represented by results from a suitable test, shall apply as follows:
- (a) studies on acute toxicity, to include
 - (i) oral LD₅₀
 - (ii) inhalational LC₅₀
 - (iii) skin irritation
 - (iv) eye irritation
 - (v) skin sensitisation
 - (vi) dermal LD₅₀ is recommended, but is not mandatory.
 - (b) repeat dose toxicity, consisting of an oral study up to 90 days, with a 28 day study as a minimum. The study protocol must include comprehensive histological, clinical biochemistry and haematological evaluation.
 - (c) genotoxicity. As a minimum, test results are required for
 - (i) point mutations in bacteria; and
 - (ii) chromosome damage in mammalian cells (*in vivo* or *in vitro*)
 - (d) A chronic/carcinogenicity study is required where genotoxicity studies yield clear or equivocal positive findings.
 - (e) Teratogenicity studies and occupational health monitoring studies are recommended but are not mandatory.
- (3) 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 disinfectant that is subject to a pre-market safety evaluation and the disinfectant contains **no new chemical entity**, a minimum data set of information on toxicity, as represented by results from a suitable test, shall apply as follows:
- (a) studies on acute toxicity, to include
 - (i) oral LD₅₀
 - (ii) inhalational LC₅₀
 - (iii) skin irritation
 - (iv) eye irritation
 - (v) skin sensitisation
 - (vi) dermal LD₅₀ is recommended, but is not mandatory.
 - (b) Occupational health and monitoring studies are recommended, but are not mandatory.
- (4) 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 disinfectant that is not subject to a safety evaluation and the disinfectant contains **no new chemical entity**, a data set comprising studies on acute toxicity as in (3)(a) above is recommended, but is not mandatory.

6. Expiry Date

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 disinfectant subject to entry on the Australian Register of Therapeutic Goods (ARTG), suitable tests must be performed to support the proposed shelf life and storage conditions.

Signed this day

(National Manager of TGA)
Delegate of the Minister of Health and Ageing

XXXXX 2005

DRAFT

The TGA Disinfectant Test

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1. Principle

The method, as applied to Hospital Grade Disinfectants or Sanitisers, is essentially that given by Kelsey & Maurer (1) for testing disinfectant performance. It is set out in a form suitable for attachment to a regulatory minimum standard for disinfectants and antiseptics. 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	<i>Ps. aeruginosa</i> <i>Pr. vulgaris</i> <i>E. coli</i> <i>S. aureus</i>	A ("clean" conditions)	2	$2 \times 10^8 - 2 \times 10^9$
		B ("dirty" conditions")		
Disinfectant - household or commercial grade	<i>E. coli</i> <i>S. aureus</i>	C	1	$2 \times 10^8 - 2 \times 10^9$
Antiseptic (excluding those for intact skin only)	<i>Ps. aeruginosa</i> <i>Pr. vulgaris</i> <i>E. coli</i> <i>S. aureus</i>	D	1	$1 \times 10^6 - 1 \times 10^7$

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. For antiseptics, the second challenge is again omitted, while Option D (serum) is selected as the choice of 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 $121^{\circ} \pm 1^{\circ}$ 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 $121^{\circ} \pm 1^{\circ}$ 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 $121^{\circ} \pm 1^{\circ}$ C for 15 minutes. Cool to room temperature.

2.3.2 Prepare Wright and Mundy medium following the author's procedure (2) or from a commercial product of the same composition (Note B) and sterilise by autoclaving at $121^{\circ} \pm 1^{\circ}$ C for 15 minutes. Cool to room temperature.

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

prepared in 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 (Note 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 2.4.1 add 30g polysorbate 80 (Note B).

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

2.4.4 Autoclave at $121^{\circ} \pm 1^{\circ}\text{C}$ 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 $37^{\circ} \pm 1^{\circ}\text{C}$ 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 $4^{\circ} \pm 1^{\circ}\text{C}$.

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 $37^{\circ} \pm 1^{\circ}\text{C}$ for 24 ± 2 hours.

3.2.4 Sub-culture from the medium in 3.2.3 into fresh medium, using an inoculating loop of 4mm in diameter. Incubate at $37^{\circ} \pm 1^{\circ}\text{C}$ for 24 ± 2 hours.

- 3.2.5 Repeat step 3.2.4 daily. For the test procedure use only those cultures which have been sub-cultured at least 5, 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 2.2) to 6 parts sterile hard water.
- 3.2.8.3 For Option C, resuspend in nutrient broth (prepared as in 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 56⁰C for 20 mins. 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 (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 $21^0 \pm 1^0$ 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 (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 3.2) and mix by swirling.
- 6.3 At 8 minutes, subculture one drop ($0.02\text{ml} \pm .002\text{ml}$) 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. (See Note 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 6.3.
- 6.6 Mix the contents of all tubes of recovery broth by vortexing. Incubate at $37^{\circ} \pm 1^{\circ}\text{C}$ 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 $37^{\circ} \pm 1^{\circ}\text{C}$ 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 $37^{\circ} \pm 1^{\circ}\text{C}$ for 48 ± 2 hours. If growth occurs, the test is considered invalid. Growth in 7.2 but not 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 3.3. Incubate at $37^{\circ} \pm 1^{\circ}\text{C}$ 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 3.3. Incubate at $37^{\circ} \pm 1^{\circ}\text{C}$ for 48 ± 2 hours, and examine for growth. If no growth occurs, the test is considered invalid. Growth in 7.3 but not in 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 7.1 or if no growth occurred in controls 7.3 or 7.4.

Should disinfectant contamination be indicated by control 7.2 on both occasions, the disinfectant is considered to fail the test. Should inadequate inactivation of the disinfectant be indicated by control 7.4 on both occasions, the test is considered invalid (Note 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 6.3 and no apparent growth in at least two of the five recovery broths specified in 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.

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
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)

GROUPING CRITERIA

Section 16 of the Therapeutic Goods Act specifies the criteria for determining what are separate and distinct therapeutic goods for the purposes of entry on the ARTG. It also determines the number of annual charges that are paid by a sponsor for maintenance of ARTG entries. For the purposes of implementation of Section 16, disinfectants are taken to be separate and distinct goods according to the criteria outlined below.

(1) Hospital grade and household/commercial grade disinfectants with specific biocidal claims. will comprise a gazetted therapeutic goods grouping if they have the following characteristics in common:

- (a) the sponsor; and
- (b) the manufacturer; and
- (c) the same Australian Device Group (ADG) classification; and
- (d) the same type ('type' as defined for this purpose is either: 'household/commercial grade with specific biocidal claims' or 'hospital grade with specific biocidal claims'); and
- (e) the same active ingredient(s) in the formulation;

and they differ from each other only in one or more of the following:

- (f) the strength or range of excipient(s); or
- (g) the concentration of active ingredient(s); or
- (h) the name; or
- (i) the directions for use; or
- (j) the type of container (disregarding container size).

(2) Hospital grade disinfectants without specific claims will comprise a gazetted therapeutic goods grouping if they have the following characteristics in common:

- (a) the sponsor; and
- (b) the manufacturer; and
- (c) the same Australian Device Group classification; and
- (d) the same active ingredient(s) in the formulation;

and they differ from each other only in one or more of the following:

- (e) the strength or range of excipient(s); or
- (f) the concentration of active ingredient(s); or
- (g) the name; or
- (h) the directions for use; or
- (i) the type of container (disregarding container size)

(3) Australian Device Groups

The following classifications will be used to include disinfectants in the ARTG. Two ADG names and codes have been allocated. All applications for inclusion in the ARTG must include the relevant ADG codes where applicable.

Disinfectant with specific biocidal claims, Code - DISIWC

A substance that is recommended by its manufacturer for application to an inanimate object to kill micro organism, and that is not represented by the manufacturer to be suitable for internal use in humans. This includes disinfectants that are claimed to be fungicides, sporicides, tuberculocides or viricide.

- * Hospital grade disinfectant
- * Household/commercial grade disinfectant
- * Surface spray disinfectant

Disinfectant without specific biocidal claims, Code - DISINF

A substance that is recommended by its manufacturer for application to an inanimate object to kill micro organisms, and that is not represented by the manufacturer to be suitable for internal use in humans. This includes disinfectants for use on non-critical surfaces.

- * Hospital grade disinfectant

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SUPPLEMENTARY NOTES

THERAPEUTIC GOODS ORDER NO. 54

STANDARD FOR HOUSEHOLD/COMMERCIAL AND HOSPITAL GRADE DISINFECTANTS

The following notes are intended to provide advice on matters which cannot readily be included in the requirements of the Order, and in particular are to:

- . explain the intention of the Order, "Standard for Household/Commercial and Hospital Grade Disinfectants";
- . draw to the attention of sponsors, other statutory requirements that may be additional to this Order; and
- . inform potential sponsors about where additional information may be obtained.

The requirements of this Order are considered to be the minimum information that should appear on the label of a disinfectant to ensure its safe use and to enable it to be traced to the sponsor and to a particular cycle of manufacture if the need arises.

In developing this Order it is recognised that there may be matters related to the use of individual products that ought to be referred to in the literature and or labelling provided by the sponsor for the product concerned, but it is not feasible to foreshadow all possibilities in a document such as this. The need to address individual product safety and use matters is not diminished by the absence of a specific requirement in this Order.

This Order is made under the *Therapeutic Goods Act 1989* and the Regulations made under that Act. There are a number of related Orders under this Act and these include:

- . Order 69 *General Requirements for Labels for Medicines*

There are provisions under the *Therapeutic Goods Act 1989* for products to be declared to be:

- . not a Medical Device (and therefore the product is a medicine or 'other therapeutic good'); or
- . not a Therapeutic Good (and therefore not subject to regulation under the Act).

The sponsors of products should ensure that their products are not within the scope of any of the above instruments. Specific matters that will or are likely to be addressed by way of the above are:

- . the possibility of some disinfectants being required to be regulated as a drug because they are substantially "skin disinfectants" (and so TGO 69 applies); and
- . the possibility of products like cleaners where, although the manufacturer's intended purpose is for the product to be a cleaner, minimal claims in respect of bactericidal action are made that might inappropriately lead the product to be regarded as a disinfectant on technical legal grounds.

Sponsors should also ensure that they comply with other Federal legislation, such as the *Commonwealth (Trade Practices) Act* which requires the name of the country in which the goods were made or produced to be included on the label.

The labelling requirements of the National Code of Practice for the labelling of workplace substances. This Code provides additional information in relation to Risk Phrases, Safety Phrases, First Aid Procedures and Emergency Procedures compared with those in the Standard Uniform Schedule for Drugs and Poisons. The Code also addresses the need for a Material Safety Data Sheet.

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