Disinfectants in Australia

**In Focus**

Disinfectants in Australia are regulated primarily through two Commonwealth agencies, being the Therapeutic Goods Administration (TGA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA). As mentioned, disinfectants are regulated as medical devices, either as surface disinfectants under Therapeutic Goods Order 54, 1996 (as amended) or as instrument disinfectants or sterilants under the *Medical Devices Regulations, 2002*. For human healthcare (TGA licensed products) a highly prescriptive and reliably vigorous testing has been established for more than a decade covering all of these disinfectants with performance criteria determined on a risk-based approach (with a regime of testing that is directly pertinent to the intended application – Table 2). Antiseptics, all of which are registered as medicines do not have a published TGA framework for standardised assessment and the TGA review process for antiseptics has been stalled since 2008.

For disinfectants used in animal health-related applications, there are no formal testing guidelines or uniform standards of performance so there can be wide variations in claims dependent upon product origins. To reduce the risks in this area, the Ausvetplan for outbreak situations relies on generalised published evidence of biocidal performance by raw material classification. Given the application context involves diseased or potentially diseased animals (and not human beings) these risks are voided by increased application volume (of the disinfectant) and quarantine measures such as isolation, movement restrictions, animal culling mass burial and incineration if required.

Table 1 outlines the most commonly used active materials.

<table>
<thead>
<tr>
<th>Antiseptic</th>
<th>Disinfectant</th>
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</thead>
<tbody>
<tr>
<td>Alcohol (ethanol or isopropanol)</td>
<td>Alcohol (ethanol or isopropanol)</td>
</tr>
<tr>
<td>Biguanides (CHG, PHMB)</td>
<td>Biguanides (CHG, PHMB)</td>
</tr>
<tr>
<td>Quaternary ammonium compounds</td>
<td>Quaternary ammonium compounds</td>
</tr>
<tr>
<td>Chloroxylenols</td>
<td>Phenols, synthetic or organic hydrogen peroxide and other oxygen releasing/containing compounds</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>Chlorine and chlorine releasing/containing compounds</td>
</tr>
<tr>
<td>Iodophors &amp; iodine compounds</td>
<td>Aldehydes (glutaraldehyde, ortho-phthalaldehyde, formaldehyde)</td>
</tr>
<tr>
<td>Antibiotic containing creams and powders</td>
<td>Glycolic and other citric acid-related materials</td>
</tr>
<tr>
<td>Tea-tree oil</td>
<td>Peracetic acid</td>
</tr>
<tr>
<td>Benzoyl peroxide</td>
<td>Ethylene oxide</td>
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</table>

The use of disinfectants can be a controversial topic, particularly in healthcare settings. The TGA has regulated the higher risk products for healthcare applications since 1996, but the impact of this regulatory framework is largely unseen in what has become a relatively condensed and specialised market place. The APVMA regulates disinfectants and sanitisers and supervises critical use through AUSVETPLAN. The use of disinfectants in healthcare is completely user-dependent and the latest literature suggests that understanding the regulatory framework and the vulnerabilities of an intended application will assist in promoting appropriate hygiene standards for surfaces and medical devices (instruments).

In Australia disinfectants seem to have an image problem. Issues such as toxicity, resistance, potency and even reliability are frequently mentioned in discussions with customer groups – particularly in healthcare settings. The irony from an Australian manufacturer’s perspective is that a disinfectant’s greatest weakness is its user dependence, that is how the disinfectant is used *in situ*. Disinfectants are highly regulated for biocidal performance standards and safety, whilst their mode of use remains entirely at the user’s discretion.

It is important to note that, despite which active raw material is used, the classification of disinfectants is dependent on application. More broadly, disinfectants intended for direct application onto humans or animals are classified as antiseptics and antiseptic products are regulated as medicines. Raw material active compounds used in antiseptic products reflect the need to balance biocidal performance with toxicity and irritancy. Disinfectants intended for application to surfaces and objects are classified as disinfectants and are regulated as medical devices in healthcare and as sanitisers in agricultural and veterinary applications. A broader and more aggressive group of active molecules can be used for disinfectants where direct human exposures are unintended. Table 1 outlines the most commonly used active materials.

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For the purposes of this review, disinfectants used in human healthcare applications are in focus.

Disinfectants are formulated to work in gross volumes (excess) rather than through very finely balanced exposures (such as with antibiotics). It is important to note that disinfectants are rarely pure chemicals, and most frequently are formulated products which contain an active material, multiple surfactants, buffers, sequestering agents, perfumes and dyes. Stability testing is required and must use validated methods as per TGA requirements.

For many situations, effective cleaning is a minimum first step prior to the use of a disinfectant. The primary risk of failure of a disinfectant in practice stems most frequently from a lack of contact between the disinfectant and the microorganisms and not from resistance transference via plasmids or related issues. Sub-lethality is an issue where the amount of contact or contact time or the contacting volumes are insufficient. Biofilms3 and fouling allow microbes to ‘hide’ from contact although in some circumstances clumping of the organisms can prevent chemical contact between the disinfectant and the microorganism. Some disinfectants will also be dramatically impacted due to interactions with soils present or factors such as pH, which can diminish biocidal performance.

The risk-based approach used by the TGA regulatory scheme uses the intended application to categorise disinfectants. The lower risk applications require a lower level of documented third party supporting evidence (independent test reports using the prescribed test protocols – see disinfectant evaluation guidelines, section 6.1). As the risk of the disinfectant application increases, so too does the regulatory intervention. For highest risk sterilants and instrument disinfectants, the required external evidentiary support for the label claims lifts to include extensive and validated pre-market submissions and also manufacturing plant licensing.

All microbiological performance tests must be conducted independently using the TGA prescribed regimen of methods. All tests must be validated by the testing laboratory and, where new or novel tests are used, the submission must provide demonstrated equivalence against the standard TGA regime. All testing laboratories must be themselves TGA-licensed.

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### Table 2. TGA disinfectant classifications and intended uses.

<table>
<thead>
<tr>
<th>Intended use</th>
<th>Tests applicable – minimum standards</th>
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<tbody>
<tr>
<td><strong>Sterilant</strong></td>
<td>critical (sterile) medical devices</td>
</tr>
<tr>
<td>Instrument disinfectant</td>
<td>semi-critical medical devices: endoscopes and similar</td>
</tr>
<tr>
<td>High level</td>
<td>breathing apparatus where TB is a risk factor</td>
</tr>
<tr>
<td>Intermediate level</td>
<td>non-critical medical devices – all types subject to materials compatibility</td>
</tr>
<tr>
<td>Low level</td>
<td></td>
</tr>
<tr>
<td><strong>Hospital-grade disinfectant</strong></td>
<td></td>
</tr>
<tr>
<td>Dirty conditions without additional claims</td>
<td>contaminated surfaces</td>
</tr>
<tr>
<td>Dirty conditions with claims</td>
<td>contaminated surfaces</td>
</tr>
<tr>
<td>Clean conditions without claims</td>
<td>otherwise clean surfaces</td>
</tr>
<tr>
<td>Clean conditions with additional claims</td>
<td>otherwise clean surfaces</td>
</tr>
<tr>
<td><strong>Commercial grade – non-healthcare</strong></td>
<td>toilet bowls and other non-healthcare surfaces</td>
</tr>
</tbody>
</table>

a. Applicable legislation is Medical Devices Regulations, 2002, and guidelines under TGO 54.

b. TGO 54, and Guidelines for the evaluation of Sterilants and Disinfectants, 1998.
or demonstrate an equivalent standard of third party quality accreditation. The basis of the risk approach underpinning the TGA scheme is the Faulding Classification scheme for medical devices. Sterilants (for critical care items) are obviously at the high end of the risk approach, whereas surface disinfectants for non-healthcare-related applications are at the low end.

One unique approach of the Australian TGA scheme is that for each classification, the product must be shown to pass the test against the standardised most-difficult-to-kill organism required for that class of product, and that this evidence must be demonstrated at the end of the shelf life and under the most strenuous allowed label conditions. This requires testing at the greatest dilution (lowest concentration of active) recommended on the label and with soiling which has 5% added organic soil and 340 ppm inorganic soil where dirty conditions are specified on the label and for all instrument disinfectants and sterilants.

By way of comparison, the EU standards use lesser amounts of organic fouling (0.3% v/v) and the United States Environment Protection Agency (EPA) requires no stability evidence past 90 days from the date of manufacture.

Although the instrument disinfectants and sterilants are widely used (primarily used for endoscopic medical devices that cannot withstand autoclaving) instances of failure with a correctly used product are ‘rare’ over years of device monitoring by the US Food and Drug Administration (FDA). In the retrospective study by Jarvis, only three of 112 reported incidents involved instrument disinfectants or sterilants and none of the reported failures involved failure of the disinfectant per se.

The causes of failure with surface hygiene within healthcare settings is a focus of on-going research and a more pertinent set of measures is being developed to eliminate false negatives in cleaning monitoring. Visual inspection remains the monitoring system most commonly used in hospitals for the routine monitoring of surface hygiene. This reliance on visual inspection has been seriously returning into focus since the study by Professor Chris Griffiths in 2000, which showed that visual inspection gave far poorer outcomes than even food industry practices using Adenosine Triphosphate (ATP) measurement. Recent work by Carling – with a new surface chemiluminence tool – showed that cleaning efficiency on over 20,000 individual high-touch objects in healthcare facilities averaged less than 50% across 14 nominated high-touch objects in all hospital areas (36 acute care hospitals participated in this study).

Choosing the most active and potentially destructive disinfectant available will be of no assistance if the application to critical surfaces is only 50% or less of those surfaces which require disinfection. Failure in the cleaning will also heighten the risk of a sub-lethal exposure to the disinfectant active, which, in turn, will increase the in-situ likelihood of resistance. This failure of application risk boxes strongly for a review of cleaning and hygiene monitoring in all healthcare settings.

It is the high-touch objects and surfaces in hospitals that are poorly cleaned which have been causally associated with the transmission within healthcare settings of multidrug-resistant organisms such as MRSA. The authors of an observational study in Rush Medical Center noted a 6% drop in the environmental recovery of VRE for every 10% improvement in cleaning of high-touch objects and surfaces within an ICU. Ensuring that cleaning and surface hygiene is correctly conducted probably applies quite widely and variability in surface hygiene performance could explain why disinfectants work sometimes and not on other occasions.

Using a ‘bug of the month’ approach to disinfectant selection may in fact be the worst possible outcome by overlooking the most significant risk of microbial survival, which is this – has the disinfectant been used correctly? Even the best disinfectant will fail if used incorrectly. The testing and licensing regime in Australia, whether through the TGA or APVMA, has provided users with products of very high standards of efficacy with independently verified and audited evidence on performance. Disinfectant users in Australia can rely on label claims right through to the expiry of shelf life, so failure in the field is more likely a failure of use, rather than of the disinfectant product.

**References**


**Biography**

**Greg Whiteley** is the Managing Director of Whiteley Corporation and has been involved in development, patenting and applied uses of cleaning and disinfecting products in healthcare for nearly 30 years. Whiteley Corporation is Australia’s largest local manufacturer of cleaning and disinfecting products for healthcare applications.