A high-level disinfectant based on accelerated hydrogen peroxide: evaluation of microbicidal activity, human and environmental safety and materials compatibility

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ABSTRACT

Semi-critical medical devices such as flexible endoscopes require high-level disinfection between each use, and glutaraldehyde is often used for this purpose due to its favorable materials compatibility. However, workplace safety and the relatively slow microbicidal activity of such formulations remain a concern. While recently introduced substitutes based on ortho-phthalaldehyde (OPA), 7.5%-14% hydrogen peroxide and 0.1%-0.3% peracids are considered less toxic than glutaraldehyde, OPA can be a potential respiratory sensitizer and the materials compatibility profile of OPA/thaldehyde is at effective concentrations remains incomplete.

This study describes a high-level disinfectant/stabilizer based on 2% accelerated hydrogen peroxide (AHP). It is a blend of hydrogen peroxide with safe inerts, which act in synergy, and has a 14-day reusable high-level disinfection and storage sterilization claim at room temperature. Evaluated using modified and internationally-accepted protocols, it has been demonstrated to be a fast-acting and broad-spectrum microbicidal active ingredient that is free from volatile organic compounds and alkyl phenol ethoxylates. Also, comprehensive materials compatibility testing has proven it to be compatible with flexible endoscopes. Furthermore, this new chemistry represents a significant advancement in the design of safer and faster-acting, high-level disinfectants.

MATERIALS AND METHODS

Formulation tested: The product tested in this study, Accel HLD 5, is a newly developed, AHP-based high-level disinfectant/sterilant. Accel HLD 5 is a blend of 2% hydrogen peroxide, sodium thiosulfate, non-ionic surfactants and stabilizers. It is free from volatile organic compounds (VOCs) and alkyl phenol ethoxylates (APEs). The formulation is registered for sale in Canada and will soon be registered in the U.S. as well.

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MATERIALS AND METHODS CONTINUED

Hydrogen Peroxide Levels and pH:

The hydrogen peroxide concentration and the pH were monitored after 7 and 14 days of stress and they did not show any significant change.

Toxicity Tests (Table 2):

Table 2: Toxicity Test Results for Accel HLD 5

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Contact Time</th>
<th>CFU per control</th>
<th>CFU per test</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacillus subtilis (ATCC 19659)</td>
<td>6 hours</td>
<td>7.79 x 10^6</td>
<td>45</td>
<td>73</td>
</tr>
<tr>
<td>Staphylococcus aureus (ATCC 7035)</td>
<td>6 hours</td>
<td>2.0 x 10^6</td>
<td>48</td>
<td>73</td>
</tr>
<tr>
<td>Escherichia coli (ATCC 6538)</td>
<td>1 min</td>
<td>2.0 x 10^4</td>
<td>73</td>
<td>91</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>1 min</td>
<td>4.9 x 10^4</td>
<td>73</td>
<td>91</td>
</tr>
<tr>
<td>Acinetobacter baumannii (ATCC 17955)</td>
<td>5 min</td>
<td>6.7 x 10^4</td>
<td>49</td>
<td>91</td>
</tr>
<tr>
<td>Trichophyton mentagrophytes (ATCC 9535)</td>
<td>5 min</td>
<td>3.2 x 10^5</td>
<td>12</td>
<td>91</td>
</tr>
<tr>
<td>Poliovirus type 1, Sabin (ATCC VR-192)</td>
<td>5 min</td>
<td>3.5 x 10^5</td>
<td>12</td>
<td>91</td>
</tr>
<tr>
<td>Adenovirus Type 5 (ATCC VR-1516)</td>
<td>5 min</td>
<td>2.63 x 10^5</td>
<td>12</td>
<td>91</td>
</tr>
</tbody>
</table>

The above results show that Accel HLD 5 is a high-level disinfectant in 5 min and a chemotherapy in 6 hours.

DISCUSSIONS AND CONCLUDING REMARKS

High-level disinfectants are required for reprocessing semi-critical medical devices such as flexible endoscopes. However, currently used products such as those based on glutaraldehyde and OPA have safety concerns due to their toxic nature. Although OPA has not been in the market for a long time, the inhalation studies suggest that as an aromatic aldehyde, it is toxic. Others such as peracids have materials compatibilities concerns. The balance between user safety, microbicidal activity and materials compatibilities has always been a huge challenge for product formulators. Traditional commercial hydrogen peroxide by itself is one of the oldest known disinfectants. It is environmentally friendly since it decomposes to water and oxygen. It is not toxic and is generated in many settings. However, its microbial activity is very slow, and the effective concentrations are corrosive to most tissues due to its oxidizing nature. It is also difficult to formulate stabilized hydrogen peroxide solutions containing other inert ingredients.

This study shows that AHP technology is now able to address these concerns. All the ingredients used in AHP formulations are on the FDA OSHA list or EPA’s exempts list. They are free from aqutic toxicants including alkyl phenol ethoxylates (APEs) that are free from VOCs, and are biodegradable.

In summary, the AHP-based high-level disinfectant tested in this study proved to be a broad-spectrum microbicidal, fast-acting, safer in nature, and the environment and compatible with flexible endoscopes.

REFERENCES

1. FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices May 13, 2005, http://www.fda.gov/cdrh/geralstnt.html
2. William N. Sokol, MD, Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA. Orthophthaldehyde (OPA) is an aliphatic aldehyde, which is even less toxic than glutaraldehyde. OPA is also faster-acting than glutaraldehyde against anaerobes, but has much higher toxicity (9). Although OPA is less toxic than glutaraldehyde, it still has some inhalation and irritation concerns. Some are described in the case of OPA-induced allergic reactions in patients undergoing surveillance cystoscopy.
3. Peracetic acids are also used as a high-level disinfectant/stabilizer. They have broad-spectrum antimicrobial activity, and are safe and corrosive to many materials.

The objective here is to report on a newly developed high-level disinfectant/stabilizer, which addresses the concerns of the above-mentioned issues. This new product is based on Accelerated Hydrogen Peroxide (AHP) technology. AHP is a synergistic blend of commonly used safe ingredients that when combined with low levels of hydrogen peroxide dramatically increase its germicidal potency and cleaning performance. AHP contains only those ingredients on the GRAS list (Generally Regarded as Safe) published by the FDA, which represent unprocessed health, safety and environmental friendly profiles.

The above results show that Accel HLD 5 is a high-level disinfectant in 5 min and a chemotherapy in 6 hours.