MICROBIOLOGICAL PROFILE

Handsan™
70% Alcohol-based hand disinfectant

Edition 6: November 2020
INTRODUCTION

HANDSAN is a ready to use, quick acting and highly effective, alcohol based hygienic hand rub.

HANDSAN is an authorised biocide UK-2019-1195-0001.

HANDSAN is bactericidal and virucidal against enveloped viruses, it evaporates from hands leaving no odour or residue.

HANDSAN is suitable for areas where food is handled, prepared and served and for areas where soap and water are not readily available.

HANDSAN is ideal for use in-between patient contact in non-surgical medical care establishments to help prevent the risk of cross infection.

The Infection Control Nurses Association (ICNA) recommends the use of an alcohol-based waterless hand rub for the following:

<table>
<thead>
<tr>
<th>Before and after patient contact</th>
<th>After removing gloves</th>
<th>Before meals/breaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>After contact with items or surfaces that are likely to be contaminated</td>
<td>Following personal hygiene measures</td>
<td></td>
</tr>
</tbody>
</table>

HANDSAN - EFFICACY SUMMARY

HANDSAN has been tested and proven to be effective against a range of micro-organisms. European Standard (EN*) test methods were used to prove efficacy against bacteria, viruses and yeast.

The UKAS accredited Microbiology Laboratory at Evans Vanodine International PLC. (Testing number 1108) performed tests with bacteria and yeast including important organisms of medical significance e.g. anti-biotic resistant bacteria. In addition, EN 1500 which involves experimental exposure of hands with *Escherichia coli* followed by application of the product was carried out by an independent laboratory.

HANDSAN has also been tested against Leptospira, Mycobacteria and viruses at independent expert laboratories using appropriate methods.

*EN - European Norm

The following tables include information of relevant, applicable test methods, conditions, contact times, organisms and diseases they can cause.
## Virus Test Profile

<table>
<thead>
<tr>
<th>Test Method Reference</th>
<th>Temp (°C)</th>
<th>Contact Time (Seconds)</th>
<th>Soil Level</th>
<th>Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 14476</td>
<td>20</td>
<td>60</td>
<td>Clean</td>
<td>Vaccinia virus</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>30</td>
<td>Clean</td>
<td>Porcine Influenza A (H1N1)</td>
</tr>
</tbody>
</table>

## Bacterial Test Profile

<table>
<thead>
<tr>
<th>Test Method Reference</th>
<th>Temp (°C)</th>
<th>Contact Time (Seconds)</th>
<th>Soil Level</th>
<th>Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN1276</td>
<td>20</td>
<td>30</td>
<td>Clean</td>
<td>Acinetobacter baumanani, Enterococcus hirae, Escherichia coli,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Escherichia coli (Extended Spectrum Beta Lactamase), Proteus</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>vulgaris, Pseudomonas aeruginosa, Shigella sonnei, Staphylococcus</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>aureus, Streptococcus pyogenes</td>
</tr>
<tr>
<td>EN 13727</td>
<td>20</td>
<td>30</td>
<td>Clean</td>
<td>Enterococcus hirae, Escherichia coli “0157”, Escherichia coli</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>K12, Staphylococcus aureus (Methicillin Resistant Staphylococcus</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>aureus), Pseudomonas aeruginosa, Salmonella typhimurium, Shigella</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>sonnei, Staphylococcus aureus, Streptococcus pyogenes</td>
</tr>
</tbody>
</table>

## Yeast Test Profile

<table>
<thead>
<tr>
<th>Test Method Reference</th>
<th>Temp (°C)</th>
<th>Contact Time (Seconds)</th>
<th>Soil Level</th>
<th>Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 13624</td>
<td>20</td>
<td>30</td>
<td>Clean</td>
<td>Candida albicans</td>
</tr>
<tr>
<td>EN 13624</td>
<td>20</td>
<td>60</td>
<td>Clean</td>
<td>Candida auris</td>
</tr>
</tbody>
</table>

## Independent Laboratory Tests

<table>
<thead>
<tr>
<th>Test Method Reference</th>
<th>Temp (°C)</th>
<th>Contact Time (Seconds)</th>
<th>Soil Level</th>
<th>Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 1500</td>
<td>N/A</td>
<td>60</td>
<td>Clean</td>
<td>Escherichia coli K12</td>
</tr>
<tr>
<td>N/A</td>
<td>RT</td>
<td>30</td>
<td>N/A</td>
<td>Leptospira interrogans</td>
</tr>
<tr>
<td>EN 14348</td>
<td>20</td>
<td>60</td>
<td>Clean</td>
<td>Mycobacterium terrae</td>
</tr>
</tbody>
</table>

N/A - Not applicable.
HAND HYGIENE TEST METHODS

Hand disinfectants can be divided into two groups, i.e. hygienic and surgical, then further divided into handwashes or handrubs.

A hygienic handwash is a product used for post-contamination treatment that involves washing hands with water.

A hygienic handrub is a product used for post-contamination treatment that involves rubbing hands without the addition of water.

Both are directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora.

Hand disinfectants can be used in a variety of areas e.g. hospitals, health care institutions, food, beverage, industrial, domestic etc. As a minimum for general hygiene purposes products should be effective against bacteria and yeast.

There are 3 claims that can be made when virus tests are used full virucidal activity, limited spectrum virucidal activity and activity against enveloped viruses. It will depend on the viruses tested which claim can be applied.

The scope of medical area EN test methods includes hygienic and surgical, handwash and handrub products and instrument disinfection by immersion and surface disinfection by wiping, spraying, flooding or other means. Areas and situations where disinfection or antisepsis is medically indicated for patient care e.g. hospitals, community medical facilities, dental institutions, clinics of schools, nurseries and nursing homes.

All EN methods define test conditions specific for the areas where the disinfectant will be applied.

Contact times in general are between 30 and 120 seconds for hygienic handwash and handrub products. However, when used in the medical area the contact time is 30 seconds for bacteria, yeast and activity against enveloped viruses. For surgical hand disinfectants the contact time should not exceed 5 minutes.

The interfering substance used in EN test methods is described as dirty or clean in medical and food, industrial, domestic, institutional areas. They simulate levels of soil encountered in practical, real-life situations.

Generally disinfectant activity improves in warm water, under clean conditions. If the temperature is less than 20°C with dirty conditions a longer contact time may be necessary.

There are two types of laboratory test method for disinfectants i.e. suspension methods and surface methods. They are both quantitative and involve using a test inoculum (mixture of test organism and interfering substance) adding the disinfectant, sampling at specified times, neutralising the sample and then calculating the number of surviving organisms. The log reductions are calculated from either the initial inoculum or a water control.

EN TEST METHODS

- **EN 1276**
  For bactericidal activity in the food, industrial, domestic and institutional areas.

- **EN 1499**
  For establishing whether a hygienic handwash product reduces the transmission of transient flora when used to wash the artificially contaminated hands of volunteers.

- **EN 1500**
  For establishing whether a hygienic hand rub reduces transient flora on artificially contaminated hands.

- **EN 13624**
  For fungicidal or yeasticidal activity in the medical area.

- **EN 14476**
  For virucidal activity in the medical area.

- **EN 14348**
  For mycobactericidal activity in the medical area. (This method is also applicable to demonstrate tuberculocidal activity).
<table>
<thead>
<tr>
<th>TEST REFERENCE</th>
<th>TEST TYPE</th>
<th>ORGANISM</th>
<th>TEST PASS CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 1500</td>
<td>N/A</td>
<td>Bacteria</td>
<td>Better than standard reference product</td>
</tr>
<tr>
<td>EN 14476</td>
<td>Suspension</td>
<td>Viruses</td>
<td>≥4 log reduction</td>
</tr>
<tr>
<td>EN 13727</td>
<td>Suspension</td>
<td>Bacteria</td>
<td>≥3 log reduction</td>
</tr>
<tr>
<td>EN 1276</td>
<td>Suspension</td>
<td>Bacteria</td>
<td>≥5 log reduction</td>
</tr>
<tr>
<td>EN 13624</td>
<td>Suspension</td>
<td>Fungi</td>
<td>≥3 log reduction</td>
</tr>
<tr>
<td>EN 14348</td>
<td>Suspension</td>
<td>Mycobacteria</td>
<td>≥4 log reduction</td>
</tr>
</tbody>
</table>

**LIST OF DISEASES OR SOURCES OF THE TEST ORGANISMS**

**VIRUS**
- Porcine Influenza A (H1N1)
  - Influenza
- Vaccinia Virus
  - Enveloped virus surrogate (including coronavirus)

**BACTERIA**
- *Acinetobacter baumannii*
  - Multiple drug-resistant infections in intensive care units
- *Enterococcus hirae*
  - Urinary tract infections
- *Escherichia coli 0157*
  - Food poisoning with possible renal failure
- *Escherichia coli ESBL (Extended Spectrum Beta Lactamase)*
  - Antibiotic resistant urinary tract infections
- *Escherichia coli K12*
  - Food poisoning
- *Leptospira interrogans*
  - Leptospirosis (Weil’s disease)
- *MRSA (Methicillin Resistant Staphylococcus aureus)*
  - Skin, bone and wound infections, pneumonia
- *Proteus vulgaris*
  - Urinary tract infections
- *Pseudomonas aeruginosa*
  - Opportunistic pathogen, wound and burn infections
- *Salmonella typhimurium*
  - Cattle derived food poisoning
- *Shigella sonnei*
  - Dysentery
- *Staphylococcus aureus*
  - Skin, bone and wound infections
- *Streptococcus pyogenes*
  - Throat infections

**YEAST**
- *Candida albicans*
  - Thrush
- *Candida auris*
  - Anti-biotic resistant yeast
LOG REDUCTION

Products claiming they will kill 99.9% of bacteria sounds extremely efficient, however it does not prove that a product is an effective disinfectant.

In order to demonstrate effectiveness disinfectants should be tested using European Standard Test Methods. Depending on the applicable area and test used, relevant log reductions are specified and must be achieved to claim effectiveness with a test method. This means a reduction in microbial numbers must be seen when compared to the number of organisms at the start of the test or, for surface tests, to a water control performed at the same time. As the numbers are large it is generally accepted that they are expressed as a logarithm. The reduction can be written as either a log value or a percentage i.e. a 5 log reduction is equivalent to a 99.999% reduction, a 3 log reduction is equivalent to 99.9% reduction.

Bacteria are microscopic free living single celled organisms. A surface contaminated with raw meat for example could have millions of bacteria per square centimetre. e.g. a surface with 1,000,000 bacteria treated with a product that kills 99.9% of bacteria would still have 1000 bacteria remaining. **If the surface was treated with a product that kills 99.999% of bacteria only 10 bacteria would remain.**

Bacterial growth rates vary depending on the surface, type and degree of soiling, temperature and presence of water. E.coli (under ideal conditions) multiplies in 15 minutes. If conditions are less than ideal e.g. lowering the temperature, or drying the surface, the growth rate slows down.

e.g. 1,000 bacteria would increase to 2,000 after 15 minutes, after 30 minutes it would be 4,000 and after 1 hour 16,000 and 256,000 after 2 hours, **10 bacteria would only have multiplied to 256 in the same 2 hour period.**

The presence of bacteria does not automatically lead to infection, the vulnerability of the person and the infectious dose (number of bacteria required to cause infection) are vitally important. Susceptible individuals such as the very young, elderly and sick are more at risk from an opportunistic infection. Some bacteria will cause an infection with less than 100 cells ingested or introduced into cuts or wounds. For this reason, it is important to reduce numbers of harmful bacteria to the lowest number possible wherever the risk of infection is high.

<table>
<thead>
<tr>
<th>LOG REDUCTION</th>
<th>NUMBER REMAINING</th>
<th>PERCENTAGE REDUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 log (Log3)</td>
<td>1,000</td>
<td>99.9%</td>
</tr>
<tr>
<td>4 log (Log4)</td>
<td>10,000</td>
<td>99.99%</td>
</tr>
<tr>
<td>5 log (Log5)</td>
<td>100,000</td>
<td>99.999%</td>
</tr>
</tbody>
</table>