

## Performance criteria

### Overview of (EN) standards, test conditions, and pass criteria

This table supports the Biocidal Products Regulation, Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, available in Volume II Efficacy Assessment and Evaluation (Parts B+C)<sup>1</sup>.

#### **NOTES to the reader:**

1. The tables provide an overview of available phase 2,1 and 2,2 EN standards which are applicable for testing the efficacy of disinfectant biocides. This overview is not exhaustive. For other, or more specific uses, and tests other than EN standards reference should be made to the relevant sections of the ECHA guidance.
2. **Please note that this is a simplified overview of the requirements. It can only be used as an aide to the requirements as stated in the ECHA Guidance. Always check the respective sections of the Guidance for additional requirements.**
3. It should be noted that although the ECHA Guidance is mainly based on EN standards, there are some cases where there are discrepancies between the Guidance and EN tests and in such cases the ECHA Guidance should be followed as the leading guidance. Where noted these are identified in the table.
4. The reader is strongly advised to check whether there are new versions of the standards on the website of the CEN : [www.cen.eu](http://www.cen.eu).
5. It should be noted that if tests other than CEN norms (notably when no CEN tests are available) are used, and pass criteria are available, these should be met (unless stated differently in this guidance). When the test does not provide pass criteria, the criteria below can be taken into account as guidance for what level of reduction is normally required.
6. In all cases, deviations from these norms are possible but should be justified in the application.
7. Regarding the table for PT 5, it should be noted that the text for PT 5 of the Guidance document (section 6) is only "**preliminary draft text**" and has **not** been reviewed or revised to address written PEG comments received. The revised version developed within the "Disinfectants Project" will undergo PEG consultation in 2017. In the meantime, the "preliminary draft text" is available to readers for information and it is for this reason that a table for PT 5 is included in this document, but this will be reviewed when Section 6 of the Guidance is reviewed.

 **PROCEDURE for updating this document**

This document can be updated or revised by submitting a request for review to the BPC Efficacy Working Group to the following email address: [BPC- WGs@echa.europa.eu](mailto:BPC-WGs@echa.europa.eu).

The request should include the following:

- Describe and explain the text to be revised giving reasons and justification for the proposed changes;
- Submit proposed revised text;
- Identify table number/name and section with page numbers of text to be reviewed and revised

<b>PT 1</b>						
<b>Product type / micro-organism</b>	<b>Requirements<sup>1</sup></b>	<b>Test required<sup>2</sup></b>	<b>Contact time<sup>3</sup></b>	<b>Temp (°C)</b>	<b>Soiling conditions<sup>4</sup></b>	<b>Required lg reduction</b>
<b>PT 1 hygienic handrub</b>						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 <sup>5</sup>	30 - 60 sec <sup>6</sup>	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 1500	30 - 60 sec <sup>6</sup>	skin T	none	≥ propan-2-ol <sup>7</sup>
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	30 - 60 sec <sup>6</sup>	20	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	30 - 60 sec <sup>6</sup>	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	30 - 120 sec <sup>6</sup>	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624/ EN 1650 <sup>5</sup>	30 - 60 sec <sup>6</sup>	20	clean / dirty	4
<b>PT 1 hygienic handwash</b>						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 <sup>5</sup>	30 - 60 sec <sup>6</sup>	20	dirty <sup>8</sup>	3 / 5 <sup>9</sup>
bacteria	Basic requirement - 2,2 test	EN 1499	30 - 60 sec <sup>6</sup>	skin T	none	> control <sup>10</sup>
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	30 - 60 sec <sup>6</sup>	20	dirty <sup>8</sup>	2 / 4 <sup>9</sup>
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	30 - 60 sec <sup>6</sup>	20	dirty <sup>8</sup>	4
viruses	Optional - 2,1 test	EN 14476	30 - 120 sec <sup>6</sup>	20	dirty <sup>8</sup>	4
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	30 - 60 sec <sup>6</sup>	20	dirty <sup>8</sup>	2 / 4 <sup>9</sup>
<b>PT 1 surgical hand disinfection</b>						
bacteria	Basic requirement - 2,1 test	EN 13727	2-3 min <sup>11</sup>	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 12791	2-3 min <sup>11</sup>	skin T	none	≥ propan-1-ol <sup>12</sup>
yeast	Basic requirement - 2,1 test	EN 13624	2-3 min <sup>11</sup>	20	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	2-3 min <sup>11</sup>	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	2-3 min <sup>11</sup>	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624	2-3 min <sup>11</sup>	20	clean / dirty	4

<b>PT 2</b>						
<b>Product type / micro-organism</b>	<b>Requirements<sup>1</sup></b>	<b>Test required<sup>2</sup></b>	<b>Contact time<sup>3</sup></b>	<b>Temp (°C)</b>	<b>Soiling conditions<sup>4</sup></b>	<b>Required lg reduction</b>
<b>PT 2 hard surfaces and other uses where EN tests are applicable, use in healthcare</b>						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 <sup>5</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697 / EN 16615 <sup>14</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4 / 5
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697 / EN 16615 <sup>14</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	3 / 4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
viruses	Optional - 2,2 test	See <sup>15</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 13697	5 min <sup>13</sup> / 60 min	20	clean / dirty	3
<b>PT 2 hard surfaces and other uses where EN tests are applicable, use other than in healthcare</b>						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 <sup>5</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697 / EN 16615 <sup>14</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4 / 5
yeast	Optional - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
yeast	Optional - 2,2 test	EN 13697 / EN 16615 <sup>14</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	3 / 4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
viruses	Optional - 2,2 test	See <sup>15</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	5 min <sup>13</sup> / 60 min	20	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 13697	5 min <sup>13</sup> / 60 min	20	clean / dirty	3

**PT 2 room disinfection (including use in healthcare)**

bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 <sup>5</sup>	as claimed	20	clean / dirty <sup>16</sup>	5
bacteria	Basic requirement - semi- field trial	NF T 72-281 <sup>17</sup>	as claimed	20	clean / dirty <sup>16</sup>	5
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	as claimed	20	clean / dirty <sup>16</sup>	4
yeast	Basic requirement - semi- field trial	NF T 72-281 <sup>17</sup>	as claimed	20	clean / dirty <sup>16</sup>	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	as claimed	20	clean / dirty <sup>16</sup>	4
mycobacteria / tuberculosis	Optional - semi-field trial	NF T 72-281 <sup>17</sup>	as claimed	20	clean / dirty <sup>16</sup>	4
viruses	Optional - 2,1 test	EN 14476	as claimed	20	clean / dirty <sup>16</sup>	4
viruses	Optional - semi-field trial	NF T 72-281 <sup>17</sup>	as claimed	20	clean / dirty <sup>16</sup>	4
fungi, fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	as claimed	20	clean / dirty <sup>16</sup>	4
fungi, fungal spores	Optional - semi-field trial	NF T 72-281 <sup>17</sup>	as claimed	20	clean / dirty <sup>16</sup>	4

**PT 2 (instrument) disinfection by immersion or filling**

bacteria	Basic requirement - 2,1 test	EN 13727	as claimed	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 14561	as claimed	20	clean / dirty	5
yeast	Basic requirement - 2,1 test	EN 13624	as claimed	20	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 14562	as claimed	20	clean / dirty	4
viruses	Basic requirement - 2,1 test <sup>18</sup>	EN 14476	as claimed	20	clean / dirty	4
viruses	Optional - 2,2 test	See <sup>15</sup>	as claimed	20	clean / dirty	4
fungal spores	Basic requirement - 2,1 test <sup>18</sup>	EN 13624	as claimed	20	clean / dirty	4
fungal spores	Basic requirement - 2,2 test <sup>18</sup>	EN 14562	as claimed	20	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	as claimed	20	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,2 test	EN 14563	as claimed	20	clean / dirty	4

<b>PT 2 textiles</b>						
bacteria	Basic requirement - 2,1 test	EN 13727 / EN 1276 <sup>5</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	5
bacteria	Basic requirement - 2,2 test	EN 16616 / ASTM E2406 / ASTM E2274 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	7 / 4 / 4
yeast	Basic requirement - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	4
yeast	Basic requirement - 2,2 test	EN 16616 / ASTM E2406 / ASTM E2274 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	6 / 3 / 3
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14348	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	4
mycobacteria / tuberculosis	Optional - 2,2 test	EN 16616 / ASTM E2406 / ASTM E2274 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	7 / 4 / 4
viruses	Optional - 2,1 test	EN 14476	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	4
viruses	Optional - 2,2 test	EN 16616 / ASTM E2406 / ASTM E2274 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	
fungal spores	Optional - 2,1 test	EN 13624 / EN 1650 <sup>5</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	4
fungal spores	Optional - 2,2 test	EN 16616 / ASTM E2406 / ASTM E2274 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty <sup>20</sup>	6 / 3 / 3

<b>PT 3</b>						
<b>Product type / micro-organism</b>	<b>Requirements<sup>1</sup></b>	<b>Test required<sup>2</sup></b>	<b>Contact time<sup>3</sup></b>	<b>Temp (°C)</b>	<b>Soiling conditions<sup>4</sup></b>	<b>Required lg reduction</b>
<b>PT 3 hard surfaces</b>						
bacteria	Basic requirement - 2,1 test	EN 1656	30 min <sup>22</sup>	10	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 14349 / EN 16437	30 min <sup>22</sup>	10	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 1657	30 min <sup>22</sup>	10	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 16438 <sup>23</sup>	30 min <sup>22</sup>	10	clean / dirty	3
fungal spores	Optional - 2,1 test	EN 1657	30 min <sup>22</sup>	10	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 16438 <sup>23</sup>	30 min <sup>22</sup>	10	clean / dirty	3
viruses	Optional - 2,1 test	EN 14675	30 min <sup>22</sup>	10	clean / dirty	4
mycobacteria / tuberculosis	Optional - 2,1 test	EN 14204	30 min <sup>22</sup>	10	clean / dirty	4
endoparasites	Optional	DGV				
<b>PT 3 hard surfaces in transport vehicles</b>						
Bacteria, yeasts, fungal spores, mycobacteria / tuberculosis, endoparasites	As PT 3 hard surfaces		5 min <sup>22</sup>		As PT 3 hard surfaces	
viruses	Basic requirement - 2,1 test	EN 14675	5 min <sup>22</sup>	10	clean / dirty	4
<b>PT 3 teat disinfection</b>						
bacteria pre-milking	Basic requirement - 2,1 test	EN 1656	30-60 sec <sup>24</sup>	30	clean / dirty	5
bacteria post-milking	Basic requirement - 2,1 test	EN 1656	5 min <sup>24</sup>	30	clean / dirty	4
bacteria pre-milking	Basic requirement - 2,2 test	to be developed	30-60 sec <sup>24</sup>	30		
bacteria post-milking	Basic requirement - 2,2 test	to be developed	5 min <sup>24</sup>	30		
yeast pre-milking	Basic requirement - 2,1 test	EN 1657	30-60 sec <sup>24</sup>	30	clean / dirty	4
yeast post-milking	Basic requirement - 2,1 test	EN 1657	5 min <sup>24</sup>	30	clean / dirty	3
yeast pre/post-milking	Optional - 2,2 test	See <sup>25</sup>				

mycobacteria / tuberculosis pre/post	Optional - 2,1 test	EN 14204	30-60 sec / 5 min <sup>24</sup>	30	clean / dirty	4
fungal spores pre/post milking	Optional - 2,1 test	EN 1657	30-60 sec / 5 min <sup>24</sup>	30	clean / dirty	3
fungal spores pre/post milking	Optional - 2,2 test	EN 16438	30-60 sec / 5 min <sup>24</sup>	30	clean / dirty	4
viruses pre/post milking	Optional - 2,1 test	EN 14675	30-60 sec / 5 min <sup>24</sup>	30	clean / dirty	4
algae	Optional	no test available				

### PT 3 hoof disinfection

bacteria	Basic requirement - 2,1 test <sup>26</sup>	EN 1656	5 min	10	dirty <sup>27</sup>	5
bacteria	Basic requirement - 2,2 test <sup>26</sup>	EN 16437	5 min	10	dirty <sup>27</sup>	4
yeast / fungal spores	Optional - 2,1 test <sup>26</sup>	EN 1657	5 min	10	dirty <sup>27</sup>	4
yeast / fungal spores	Optional - 2,2 test <sup>26</sup>	EN 16438 <sup>23</sup>	5 min	10	dirty <sup>27</sup>	3
viruses	Optional - 2,1 test <sup>26</sup>	EN 14675	5 min	10	dirty <sup>27</sup>	4 / 5
mycobacteria / tuberculosis	Optional - 2,1 test <sup>26</sup>	EN 14204	5 min	10	dirty <sup>27</sup>	4

### PT 3 disinfection of hatching-eggs

bacteria	Basic requirement - 2,1 test	EN 1656	as claimed	30	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 16437	as claimed	30	clean / dirty	4
fungal spores	Basic requirement - 2,1 test	EN 1657	as claimed	30	clean / dirty	4
fungal spores	Basic requirement - 2,2 test	No standard guideline available <sup>28</sup>	as claimed	30	clean / dirty	3
other target organisms	Optional - 2,1 test	As PT 3 porous surfaces				
other target organisms	Optional - 2,2 test	As PT 3 porous surfaces				

### PT 3 textile disinfection

bacteria	Basic requirement - 2,1 test	EN 1656	as claimed	as claimed <sup>19</sup>	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 16616 / ASTM E2406 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty	7 / 4
yeasts	Basic requirement - 2,1 test	EN 1657	as claimed	as claimed <sup>19</sup>	clean / dirty	4
yeasts	Basic requirement - 2,2 test	EN 16616 / ASTM E2406 <sup>21</sup>	as claimed	as claimed <sup>19</sup>	clean / dirty	6 / 3



other target organisms	Optional - 2,1 test	As PT 2 textile, with PT 3 soiling				
other target organisms	Optional - 2,2 test	As PT 2 textile, with PT 3 soiling				
<b>PT 3 disinfection of beehives and beekeeping equipment</b>						
bacteria	Basic requirement - 2,1 test	EN 1656	as claimed	10	clean/dirty	5
bacteria	Basic requirement - 2,2 test	EN 16437	as claimed	10	clean/dirty	4
bacterial spores	Basic requirement - 2,1 test	EN 13704	as claimed	10	clean/dirty	4
bacterial spores	Basic requirement - 2,2 test	EN 16437 adapted	as claimed	10	clean/dirty	3
other target organisms	Optional - 2,1 test	As PT 3 porous surfaces				
other target organisms	Optional - 2,2 test	As PT 3 porous surfaces				

<b>PT 4</b>						
<b>Product type / micro-organism</b>	<b>Requirements<sup>1</sup></b>	<b>Test required<sup>2</sup></b>	<b>Contact time<sup>3</sup></b>	<b>Temp (°C)</b>	<b>Soiling conditions<sup>4</sup></b>	<b>Required lg reduction</b>
<b>PT 4 hard surfaces</b>						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	20	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	20	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	as claimed	20	clean / dirty	3
mycobacteria	Optional - 2,1 test	EN 14348	as claimed	20	clean / dirty	4
viruses	Optional - 2,1 test	EN 14476 <sup>29</sup>	as claimed	20	clean / dirty	4
viruses	Optional - 2,2 test	See <sup>15</sup>				
bacteriophages	Optional - 2,1 test	EN 13610 <sup>29</sup>	as claimed	20	clean / dirty	4
fungal spores	Optional - 2,1 test	EN 1650	as claimed	20	clean / dirty	4
fungal spores	Optional - 2,2 test	EN 13697	as claimed	20	clean / dirty	3
bacterial spores	Optional - 2,1 test	EN 13704	as claimed	20	clean / dirty	3
<b>PT 4 inner surfaces without circulation</b>						
see PT04 hard surfaces			as claimed	as claimed <sup>30</sup>		
<b>PT 4 inner surfaces by CIP</b>						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	as claimed <sup>30</sup>	clean / dirty	5
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	as claimed <sup>30</sup>	clean / dirty	4
other target organisms	see PT 4 hard surfaces					
<b>PT 4 surfaces in drinking water systems</b>						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
Legionella	Optional - 2,1 test	EN 13623	as claimed	20	clean / dirty	5
other organisms when claimed	Optional - 2,1 test	as PT 4 hard surfaces				

Legionella	Basic requirement field trial	See 5.6.2.1.2				
bacteria	Optional - field trial	See 5.6.2.1.2				
<b>PT 4 equipment disinfection by soaking</b>						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	as claimed	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed	clean / dirty	4
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	as claimed	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed	clean / dirty	3
other organisms when claimed	Optional - 2,1 test	as PT 4 hard surfaces				
other organisms when claimed	Optional - 2,1 test	as PT 4 hard surfaces				
<b>PT 4 surfaces in veterinary water systems</b>						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	20	clean / dirty	4
other organisms when claimed	Optional - 2,1 test	as PT 4 hard surfaces				
<b>PT 4 disinfection in dishwashing machines and crate washers</b>						
bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	as claimed <sup>19</sup>	clean / dirty	5
bacteria	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed <sup>19</sup>	clean / dirty	4
bacteria	Basic requirement - 3 test	DIN SPEC10534	as claimed	as claimed <sup>19</sup>	clean /dirty	
yeast	Basic requirement - 2,1 test	EN 1650	as claimed	as claimed <sup>19</sup>	clean / dirty	4
yeast	Basic requirement - 2,2 test	EN 13697	as claimed	as claimed <sup>19</sup>	clean / dirty	3
yeast	Basic requirement - 3 test	DIN SPEC10534	as claimed	as claimed <sup>19</sup>	clean / dirty	
other organisms when claimed	Basic requirement - 2,1 test	as PT 4 hard surfaces				
other organisms when claimed	Basic requirement - 2,2 test	as PT 4 hard surfaces				
other organisms when claimed	Basic requirement - 3 test	According to DIN SPEC 10534				

**PT 5 Please note that PT 5 entries are preliminary**

<i>Product type / micro-organism</i>	<i>Requirements<sup>1</sup></i>	<i>Test required<sup>2</sup></i>	<i>Contact time<sup>3</sup></i>	<i>Temp (°C)</i>	<i>Soiling conditions<sup>4</sup></i>	<i>Required lg reduction</i>
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**PT 5 drinking water for drinking water companies, stationary water in reservoirs and undefined water**

bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
bacteria	Basic requirement - simulated use test	Test protocol in guidance	as claimed	20	clean / dirty	see guidance
viruses	Basic requirement - 2,1 test	EN 14476	as claimed	20	clean / dirty	4
viruses	Basic requirement - simulated use test	Test protocol in guidance	as claimed	20	clean / dirty	see guidance
other organisms when claimed	Optional - 2,1 test	as PT 4 hard surfaces				

**PT 5 drinking water in collective systems**

bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean	5
Legionella	Basic requirement - 2,1 test	EN 13623	as claimed	20	clean	5
Legionella	Basic requirement - field trial	See 6.2.1.2.2				

**PT 5 drinking water for animals**

bacteria	Basic requirement - 2,1 test	EN 1276	as claimed	20	clean / dirty	5
other organisms when claimed	Optional - 2,1 test	as PT 4 hard surfaces				
claimed organisms	Basic requirement simulated-use or field trial					

## **NOTES on TABLES**

- <sup>1</sup> Requirements: basic requirements are mandatory and have to be fulfilled for authorisation of a product with this intended use. In addition, other organisms claimed are optional, i.e. if the requirements for these organisms are not fulfilled these organisms will be excluded from the claim.
- <sup>2</sup> EN-tests are strongly advised but not mandatory. Other tests carried out according to standard guidelines are acceptable if a clear description of the test procedure (including contact time, soiling, temperature, suitable controls, log<sub>10</sub> reduction, etc.) and justification is provided.
- <sup>3</sup> Contact time: maximum acceptable contact times are stated, at which efficacy should be demonstrated. If a shorter contact time is stated on the label, efficacy has to be demonstrated at this shorter contact time. It is recommended to only use contact times mentioned in the EN standards as obligatory or additional contact time, to keep the robustness of the test as much as possible.
- <sup>4</sup> Soiling conditions: low level soiling conditions are acceptable if it is stated on the label that cleaning prior to disinfection is necessary. Otherwise, and in case no prior cleaning is possible, dirty conditions have to be included in the tests.
  - PT 1 and 2** For hospitals and health care:
    - Dirty 3 g/L bovine albumin + 3 ml/L sheep erythrocytes // Clean 0.3 g/L bovine albumin.
  - PT 1 and 2** other uses:
    - Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin.
  - PT 2** cosmetic industry:
    - Dirty 3 g/L bovine albumin **and** 5g/L sodium dodecyl sulphate in separate tests.
  - PT 2** surfaces in agricultural area (no plant protection claim):
    - Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin.
  - PT 3** general hard surface disinfectants, hoof and animal skin disinfection, pre-milking teat disinfection, and eggs in hatcheries:
    - Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin.
  - PT 3** outer surfaces of milking equipment:
    - Clean/Dirty 10g/L skimmed milk
  - PT 3** teat disinfection:
    - pre milking: Dirty 10 g/L bovine albumin + 10 g/L yeast extract // Clean 3 g/L bovine albumin (different from EN14885).
    - post milking: Clean/Dirty 10g/L skimmed milk.
  - PT 3** textiles:
    - depending on the use, either milk soiling (see teat disinfection) or veterinary soiling (see PT 3 general) would be the relevant type of soiling. However, since the phase 2, step 2 test for textile are not validated for this type of soiling, consultation with CEN is needed. For the time being, it is recommended to use the obligatory interfering substance in EN 16616: sterile defibrinated sheep blood (12.5 ml sheep blood per kg textile).
  - PT 4** general disinfection in food industry and other area's with surfaces in contact with food:
    - Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin.
  - PT 4** milk industry and milking equipment on farms:
    - 10g/L skimmed milk.
  - PT 4** meat industry:
    - Dirty 3 g/L bovine albumin + 3 ml/L sheep erythrocytes (different from EN 14885).
  - PT 5** general:
    - Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin.
    - Legionella* (EN 13623) yeast extract at concentration of 0.0005%.

- <sup>5</sup> For PT 1 or PT 2-'medical applications' the required tests differ from PT 1 or PT 2-'non-medical' applications. The first test is for medical applications and the second is for non-medical applications. In case both types of applications are claimed, only one test has to be carried out, in which the relevant worst case test conditions (in general medical test) are included.
- <sup>6</sup> For hygienic handwash and handrub products used in **hospitals** the contact time is usually 30 seconds, for other uses the contact time is between 30 and 60 seconds (up to 120 seconds in case of virucidal activity). Please note that some EN tests were not developed for hand disinfection and therefore contact times shall be adapted.
- <sup>7</sup> According to EN 1500 the test is passed when the mean reduction achieved by the hygienic handrub product under test is at least not inferior to that achieved by a reference handrub with propan-2-ol 60 % (v/v) ( $p=0.025$ ).
- <sup>8</sup> For handwash disinfectants it is assumed that hands will not be washed before washing with a disinfectant. Therefore, tests have to be done under dirty conditions.
- <sup>9</sup> The required lg reduction in EN 13727 / EN 13624 is lower than in EN 1276 / EN 1650, as in EN 13727 and EN 13624 for hygienic handwash products the highest accepted concentration tested is 50%.
- <sup>10</sup> According to EN 1499 the test is passed when the mean reduction achieved by the hygienic handwash with the product under test is larger than that achieved by a specified reference hygienic handwash (unmedicated liquid soap) ( $p=0.01$ ).
- <sup>11</sup> The WHO states that for several products, scrubbing for 2-3 minutes reduces bacterial counts to acceptable levels. However, in the past, longer scrubbing times were accepted. Contact times of longer than 3 minutes, and up to 5 minutes, will only be authorised with a sound justification on the necessity of such long scrubbing times. Shorter contact times are accepted when tested at this contact time.
- <sup>12</sup> According to EN 12791 the test is passed when the mean reduction achieved by the surgical handrub product under test is at least not inferior to that achieved by a reference handrub with propan-1-ol 60 % (v/v).
- <sup>13</sup> Products intended to disinfect surfaces that are likely to come into contact with the patient and / or the medical staff and surfaces, which are frequently touched by different people, leading to the transmission of microorganisms to the patient, must be tested with a contact time of maximum 5 min. The same applies where the contact time of the product must be limited for practical reasons. Products for other surfaces than stated above may be tested with a contact time of maximum 60 min.
- <sup>14</sup> When a surface disinfectant is a wipe soaked with disinfectant liquid the product should be tested in the EN 16615 test (phase 2, step 2), with mechanical action.
- <sup>15</sup> For PT 2: as a phase 2, step 2 an EN medical area test with adenovirus and murine norovirus may be used (as soon as available). Please note that although the virucidal claim for PT 2 includes testing against poliovirus, it is not required to test against this test species in the phase 2, step 2 test.  
For PT 4: either a modified EN medical test or, as soon as available, an EN food area test with Murine Norovirus.
- <sup>16</sup> This test includes the use of milk as an interfering substance in order to maintain viability of the micro-organisms on the carriers during the test. Depending on the area of use, other suitable interfering substances should be tested (e.g. blood for use in hospitals).
- <sup>17</sup> NF T 72-281 is a test from AFNOR, the French standardisation body. This standard is taken as a start to develop a new EN standard on airborne disinfection of surfaces. Where available an EN test may be used for a semi-field method which evaluates the efficacy of disinfectants when vaporised in a room.
- <sup>18</sup> For medical equipment, tests with fungi and viruses are a basic requirement. For all other equipment, tests with fungi and viruses are optional.
- <sup>19</sup> When the product is intended to be used at high temperatures (e.g.  $>40$  °C) relevant test organisms for these temperatures should be used. See 1.4.4.4 of the guidance.
- <sup>20</sup> The interfering substance most appropriate for the in-use conditions should be used. For instance, blood for products used in the medical area and protein for products used in industry, institutional and domestic areas are recommended. The soiling on a domestic product for use in pre-soak (dirty clothes) will be very much higher than

the soiling present for a post-wash rinse additive (clean clothes). For products used during pre-soak and wash, tests should be done under dirty conditions. For products used during post-wash rinse, tests should be done under clean conditions. EN 16616: The obligatory interfering substance to be tested is sterile defibrinated sheep blood (12.5 ml sheep blood per kg textile).

<sup>21</sup> EN 16616 should be used for biocidal products used in washing machines. For products not intended to be used in washing machines, small scale laboratory setting (e.g. for pre-soaking in a bucket) may be considered (e.g. ASTM E4206 or ASTM E2274).

<sup>22</sup> For surface disinfection in veterinary areas the normal contact time is 5 minutes. The maximum contact time is 30 minutes. For surface disinfection on animal transport vehicles the maximum contact time is 5 minutes. For disinfectants used on boots applied by spraying or walk-through bath the contact time should not exceed 1 minute.

<sup>23</sup> As soon as a phase 2, step 2 test for porous surfaces are available these should be used (where relevant).

<sup>24</sup> For post-milking teat disinfection the normal contact time is 1 minute. The maximum contact time is 5 minutes. For pre-milking teat disinfection the normal contact time is 10-30 seconds. The maximum contact time is 60 seconds.

<sup>25</sup> Presently there are no standard phase 2, step 2 tests for yeasts for teat disinfectants. As soon as a validated teat disinfectant phase 2, step 2 test is available for yeasts, this should be used.

<sup>26</sup> For disinfection in a hoof bath, information should be provided on how long the efficacy of a hoof bath can be guaranteed. This can be done in a challenge test or a field test. See the guidance chapter 4.4.2.1 for more details.

<sup>27</sup> For hoof disinfection it is not anticipated that hoofs will be cleaned sufficiently before disinfection in practice. Therefore only tests under dirty conditions are acceptable.

<sup>28</sup> As long as no standard phase 2, step 2 tests are available it is not obligatory to provide these tests. Phase 2, step 2 tests have to be provided as soon as standard tests are available.

<sup>29</sup> For uses where efficacy against bacteriophages only is claimed, EN 13610 can be employed. For all other PT 4 uses where virucidal activity is claimed EN 14476 should be used with Norovirus and Adenovirus as test organisms.

<sup>30</sup> The test temperature should be according to the use instructions on the label: e.g. cold = 4, 10 °C, no restriction = 20 °C, high temp = 40, to 80 °C. When the product is intended to be used at high temperatures relevant test organisms for these temperatures should be used. See 1.4.4.4 of the guidance.