Efficacy Assessment for PT1 to PT5 Biocidal Products

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MAIN GROUP 1: disinfectants

No products without a claim for disinfection

- PT1 (human hygiene)
- PT2 (Disinfectants and algaecides not intended for direct application to humans or animals)
- PT3 (Veterinary hygiene)
- PT4 (Food and feed area)
- PT5 (drinking water)
Check for correct reference directive/regulation

PT1 (human hygiene)

BPR (intact skin, scalp)

2001/83/EC
1223/2009
93/42/EEC

To be noted: products for wound disinfection or pre-operative skin disinfection before surgery and disinfection before injection are under the 2001/83/EC
Check for correct reference directive/regulation

- **PT3 (Vet)**
  - BPR (Vet hygiene, surfaces&equipment)
  - 2001/82/EC amended by 2004/28/EC

- **PT4 (food&feed)**
  - BPR (surfaces, equipments, container, utensils, etc)
  - 852/2004
  - 853/2004
  - 854/2004
What infos must be provided

Tests to verify efficacy of a product /a.s.

- Claim(s)
- Area of application
- Directions for use
Claim

- The purpose (e.g. prevent biodeterioration, disinfect surfaces);
- The function of the product (e.g. bactericide, wood preservative, repellant, etc.);
- The (group of) target organisms to be controlled;
- In-use concentration;
- Use conditions and area of use;
- The effect which will result from using the product on the target organisms (e.g. kill, control, repel, prevent, etc.);
- Any products, organisms or objects to be protected.
Area of application/directions for use

- Use in hospitals, swimming pools, bathrooms, on textiles, etc

- Contact time/method(s) of application

- Resistance:
  - incorporation of appropriate label warnings;
  - application with one or more biocidal active substances to enhance efficacy;
  - alternate use of biocides based on a.s. with different mode of action;
  - periodical switch to a different a.s. to which resistance rarely or never develops.
Tiered approach for efficacy testing

- Phase 1 tests are screening tests not related to in-use conditions.
- Phase 2/step 1 tests are quantitative suspension tests to establish that a product has -cidal activity, simulating practical conditions appropriate to its intended use.
- Phase 2/step 2 tests are quantitative laboratory tests, on carriers or living tissues with dried-on micro-organisms, simulating practical conditions to establish that the product has a -cidal activity.
- Phase 3/field tests
Test report

- Introduction
- Materials and Methods (e.g. tested product composition, conditions of the test temperature, humidity,)
- Tested organisms
- Results and raw data
- Conclusion/discussion based on criteria defined in guidance
Tests to evaluate efficacy of a.s/products

EN 14885

Claim matrices on BPR
<table>
<thead>
<tr>
<th>Product description type</th>
<th>Use area</th>
<th>Target site</th>
<th>Purpose</th>
<th>Min spectrum of activity</th>
<th>Additional optional activity</th>
<th>User Type</th>
<th>Application type</th>
<th>Appropriate methodology</th>
<th>Appropriate performance standard relevant to target site</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Hard surface biocidal product</td>
<td>health care</td>
<td>hospital rooms, bathroom, operation room, laboratories, dental centres, isolation rooms</td>
<td>reduce risk of infection</td>
<td>bacteroicidal and yeasticidal</td>
<td>fungicidal virucidal sporidicial mycobactericidal tuberculicidal</td>
<td>professional</td>
<td>spraying, wiping, mopping, scrubbing, foaming, flooding</td>
<td>suspension and surface lab tests</td>
<td>EN 14885 (medical area) and when not applicable OECD 187 as appropriate</td>
</tr>
<tr>
<td>2 Hard surface biocidal product</td>
<td>industry, (e.g. cosmetic, pharmaceutical), institutions, health care facilities</td>
<td>hard surfaces, e.g. floors, walls, work surfaces, kitchen surfaces (excluding food contact surfaces), bathroom seats, toilet bowls (outside), outdoor surfaces</td>
<td>reduce risk of infection, prevention of product contamination and to prevent product spoilage</td>
<td>bacteroicidal and yeasticidal</td>
<td>fungicidal virucidal sporidicial</td>
<td>professional</td>
<td>spraying, wiping, mopping, scrubbing, foaming, flooding</td>
<td>suspension and surface lab tests</td>
<td>EN 14885 (institutional area, domestic area, industrial area; virucidal: medical area) and when not applicable OECD 187 as appropriate</td>
</tr>
<tr>
<td>3 Hard surface biocidal</td>
<td>institutions, health care facilities,</td>
<td>hard surfaces, e.g. kitchen surfaces (excluding food)</td>
<td>reduce risk of infection, prevention of</td>
<td>bacteroicidal and yeasticidal</td>
<td>fungicidal virucidal sporidicial</td>
<td>professional</td>
<td>impregnated wet wipes</td>
<td>suspension tests + surface lab</td>
<td>EN 14885 (relevant area (EN 16615)</td>
</tr>
<tr>
<td>Product description type</td>
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</tr>
<tr>
<td>product</td>
<td>industry</td>
<td>contact surfaces), bathroom, hospital rooms, dentists, isolation rooms</td>
<td>product contamination and to prevent product spoilage</td>
<td>mycobactericidal</td>
<td>tuberculocidal</td>
<td>professional</td>
<td>spray, wipe</td>
<td>suspension and surface lab tests</td>
<td>EN 14885 (relevant area)</td>
</tr>
<tr>
<td></td>
<td>institutions, health care facilities, industry</td>
<td>surfaces, e.g. bathroom surfaces and cellars, outdoor surfaces</td>
<td>anti-staining and reduction of fungal spores with allergenic potential</td>
<td>fungicidal</td>
<td>n.a.</td>
<td>professional</td>
<td>spraying, wiping, scrubbing</td>
<td>suspension and surface lab test (if available) or field trial</td>
<td>to be developed, field trial demonstrating difference before and after treatment</td>
</tr>
<tr>
<td>Hard surface biocidal product</td>
<td>institutions, health care facilities, industry</td>
<td>indoor or outdoor surfaces</td>
<td>anti-staining, anti-slippping</td>
<td>algaecidal</td>
<td>n.a.</td>
<td>professional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Hard surface biocidal product</td>
<td>institutions</td>
<td>surfaces, e.g. kitchen surfaces (excluding food contact surfaces), bathroom surfaces, toilet seats, outdoor surfaces, drains, e.g. bathroom, sink plug</td>
<td>control of malodour caused by micro-organisms</td>
<td>bacterio-static and/or fungicidal</td>
<td>fungicidal</td>
<td>professional</td>
<td>spraying, wiping, mopping, scrubbing, foaming, flooding</td>
<td>lab tests and odour panel test</td>
</tr>
</tbody>
</table>
Introduction to EN tests

This (EN14885) European Standard specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants and antiseptics in order to support claims that they have specific properties appropriate to their intended application. These laboratory methods may also be used for active substances and products under development.

.....

Chemical disinfectants and antiseptics should always be used responsibly. This should take into account the environmental impact of inappropriate product in-use concentrations (too high or too low) and of unnecessary use.
Tests to evaluate efficacy of a.s.

- Screening tests (EN1040, EN1275, EN14347)

The evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

- Semi-field or field tests
Tests to evaluate efficacy of products

- Screening tests (EN1040, EN1275, EN14347)
- Lab tests
- Simulation tests
- Semi-field or field tests
With rare exceptions

- a quantitative suspension test (phase 2/step 1)
- a quantitative carrier test (phase 2/step 2);
  - both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.)
- When necessary, a semi-field or a field test
**Phase2/step1 EN tests**

- Quantitative suspension tests to verify –cidal activity in simulating in-use conditions

<table>
<thead>
<tr>
<th>PT2, PT4</th>
<th>PT3</th>
<th>PT1</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN1276 (bactericidal)</td>
<td>EN1656 (bactericidal)</td>
<td>EN13727 (bactericidal)</td>
</tr>
<tr>
<td>EN1650 (fungicidal)</td>
<td>EN1657 (fungicidal)</td>
<td>EN13624 (fungicidal)</td>
</tr>
<tr>
<td>EN13610 (virucidal vs bacteriophages)</td>
<td>EN14204 (mycobactericidal)</td>
<td>EN14348 (mycobactericidal)</td>
</tr>
<tr>
<td>EN13704 (sporidical)*</td>
<td>EN14675 (virucidal)</td>
<td>EN14476 (virucidal)</td>
</tr>
<tr>
<td>EN12623 (legionella)</td>
<td></td>
<td>prEN17126 (sporidical)</td>
</tr>
</tbody>
</table>
## Phase2/step2 EN tests

- Quantitative tests simulating in use conditions

<table>
<thead>
<tr>
<th>PT2, PT4</th>
<th>PT3</th>
<th>PT1</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN13697 (bactericidal/fungicidal on surface) EN16616 (textile) EN16615 (bactericidal/yeasticidal with mechanical action-wipes)</td>
<td>EN14349 (bactericidal NP surfaces) EN16437 (bactericidal P surfaces) EN16438 (fungicidal NP surfaces)</td>
<td>EN1499 (handwash) EN1500 (handrub) EN12791 (surgical handrub) EN14561 (bactericidal-instruments) EN14562 (fungicidal-instruments) EN14563 (mycobactericidal-instruments) EN16615 (bactericidal/yeasticidal with mechanical action-wipes) prEN16777 (virucidal)</td>
</tr>
</tbody>
</table>
Others

- Chemothermal disinfection – EN 16616.
- NF T 72-281 for room disinfection
- Virucidal claim for PT4 products – adapt EN14476 (PT1) with the interfering substance(s) used in PT4-dedicated norms
For high $T^\circ$ applications

- If products (PT 2-4) are tested with high temperatures above 40ºC:
  - *E. faecium* for bactericidal activity
  - MPV for virucidal claim
  - Spores of *B.cereus* or *C.sporogenes* for sporicidal claim

- For mycobacteria, yeasts and fungal spores no relevant test organisms for high temperatures are available. Most yeasts and fungal spores are already irreversibly inactivated by high temperature (>40 ºC) in the control without active substance. However, ascospores of several fungi can become heat resistant and can cause problems in, for instance, the food industry.

- When efficacy against mycobacteria, yeasts and fungal spores is claimed and no temperature resistant strains are available, the standard test organisms should be tested at the maximum temperatures for which the test is validated.

- For specific claims against heat resistant species (e.g. *Talaromyces flavus*) efficacy tests with these organisms should be provided. In these tests a control without biocide should be included which shows survival of the test organisms at the high test temperature.
PT2

• NF T 72-281 for room disinfection
  • Does not disinfect the air!

• Swimming pools/hot tubs/etc
  • a quantitative suspension test (phase 2, step 1);
  • simulated-use tests with pool water or a surface test (phase 2, step 2)
  • and a field test (phase 3) - "Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants in Laboratory and Field testing" (OECD Series n. 170, Oct 2012)
  • algicidal claim (?)
  • biofilm claim (?) (also
Biofilm claim

- Phase2/step1 suspension test

- Simulated test conditions (static conditions/flow conditions) considering the claim:
  - disruption of biofilm?
  - Inhibition of biofilm formation?
  - Mono or multispecies biofilm?

- Field test

To generate standard biofilm: CEN/ISO15883-5 (annexF) – ASTM E2196 and ASTM 2562
PT2

- Textiles

  - phase 2/step 1 suspension tests as described in EN 14885

  - phase 2/step 2 tests involving
    - a full-scale laundry machine test (EN 16616)
    - 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).
Water systems are disinfected in closed circuits, after which the system is washed with clean water?

Disinfection is done in the water system while it is in service and the water itself is also disinfected?

PT4 or PT5?

PT4

PT5
Data to support efficacy of a product to be utilized in water distribution systems (disinfection of pipework) (PT4)

- Quantitative suspension test phase 2/step 1 – food area
- Quantitative suspension test for Legionella (EN13623)
- Field tests (phase 3)
- Claim vs biofilm
Disinfection for the drinking water suppliers and their water distribution systems
Disinfection of raw water for individual supply (1-2 premises)
Disinfection in collective drinking water systems
Disinfection of water in reservoirs
Disinfection of water of undefined quality for small scale use (up to 5 L/person/day)
Disinfection of water for animals
Drinking water suppliers & their water distribution system

- Quantitative suspension test phase 2/step1 (bactericidal, fungicidal, etc) – food area
  - Modified to reflect in use-conditions (T° range, soiling, time of contact)

- Simulated-use test

- Challenge test x secondary disinfection

Efficacy against bacteria and virus. Other MOs (i.e. protozoa) only if specified in the claim
Raw water for Individual supply

- Quantitative suspension test phase 2/step1 (bactericidal, fungicidal, etc) – food area
  - Modified to reflect in use-conditions (T° range, soiling, time of contact)

- Simulated-use test
Collective drinking water systems (hospitals, hotels, etc)

- Laboratory tests
  - Quantitative suspension phase2/step1 tests
  - Quantitative suspension test for Legionella (EN13623)- Modified to reflect in use-conditions (T° range, soiling, time of contact)*

- Simulated-use test / Field trial
  - Locations/duration of the tests/Typer of water/legionella conc/sampling points
Water in reservoirs (ships, mobile house, dentistry chairs, etc)

- Suspension tests phase2/step1 – food area / challenging efficacy test (Mos/soiling)

Water of undefined quality

- Suspension tests phase2/step1 – food area (Modified to reflect in use condition)
Water for veterinary use

- Quantitative suspension test phase2/step1 – food area
- Simulated-use test or Field trial
- Biofilm (if applicable)
TREATED ARTICLES

• Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products (from CA-Sept 13 Doc5.1-rev Dec14).

1.0 Does the object meet the definition of an article as given in REACH?*

Y

The object is an article as defined under REACH, or a combination of an article and a substance/mixture

N

The object is a substance or a mixture as defined under REACH
Active substances notified for PTs 1-5 (Main group 1) are usually used in (liquid) biocidal products as for instance hand disinfection or surface disinfection products. These products are clearly considered biocidal products. But sometimes active substances belonging to PTs 2, 3 or 4 are incorporated into textiles and other solid materials; the protection of the material itself is not intended, but a new property is introduced to an article, intended to protect its user. For such claims, testing is particularly challenging and the specific conditions of use have to be considered when designing the efficacy testing.
The assessment of an active substance is done on the basis of a representative product, and the active substance is approved if at least one biocidal product containing that substance is expected to meet the criteria for authorisation. This implies that, as a general rule, not all possible uses of an active substance are considered at the time of approval.

<table>
<thead>
<tr>
<th>PT1 (human hygiene disinfectants)</th>
<th>Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT2 (disinfectants)</td>
<td>Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.</td>
</tr>
<tr>
<td>PT3 (veterinary hygiene products)</td>
<td>The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles.</td>
</tr>
<tr>
<td>PT4 (food and feed area disinfectants)</td>
<td>Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.</td>
</tr>
<tr>
<td>PT5 (drinking water disinfectants)</td>
<td></td>
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</tbody>
</table>
Guidance document on Tier-2 laboratory based tests used to substantiate claims for efficacy of biocide treated articles – deadline for comments dec 2017
(http://www.oecd.org/env/ehs/testing/Tier%20II%20GD%20efficacy%20of%20treated%20articles_website.pdf)
What infos must be provided

- Tests to verify efficacy of a product /a.s.
- Claim(s)
- Area of application
- Directions for use
Label

- Intended use
- Site of application
- Spectrum of activity
- Directions for use
Label

- Clear instructions for use
- Avoid
  - general indication such as «fast acting» or directions too difficult to follow (i.e. for a concentrated product «... dilute to 1,5%)
  - names of target Mos
- Specify the contact time
Thanks for your attention