STERISAFE®

Can I trust the efficacy claims of my airborne disinfectant product?

The high standards of NF T 72-281

Date: October 2019

NF T 72-281

The NF T 72-281 standard is a protocol designed by the French standardisation body AFNOR. It is designed for airborne surface disinfection systems, and it is recognized for its particularly strict fulfilment conditions. NF T 72-281 defines a set of testing methods to challenge disinfectant products in real-life conditions; efficacy data is obtained after tests conducted only according to the intended manner of use. When considering any airborne disinfectant instrument, it is important to verify compliance with NF T 72-281.

NF T vs existing EN

AFNOR published the first version of NF T 72-281 in 1980, and has updated it a number of times since, with the latest iteration being in 2014 (NF T 27-281:2014). The necessity for this standard lies in the unsuitability of existing standardised test methods for biocidal materials delivered via air. Current European standards (EN) testing for the efficacy of disinfecting agents only test by direct application methods; meaning the allegedly biocidal product is in liquid form, and either submerged or directly entering in contact with target microorganisms. Those types of testing are usually considered to be of type "Phase 1"; and while they are a good indicators of the biocidal nature of the tested substances, Phase 1 tests are not representative of the real-life usage of biocidal agents. This is a particularly important distinction in the case of airborne disinfectants, where active agents are delivered as gas, vapour, mist or fog, and have completely different parameters of action (concentration, surface contact and time).

Because regulatory bodies are aware of this issue, they currently use NF T 72-281 as the starting point for a new EN standard dedicated to airborne disinfection systems (prEN 17272). In the meanwhile, the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) only accepts the NF T 72-281 standard for airborne surface disinfection systems. So when choosing an airborne disinfecting instrument, it is highly recommended to select a product that uses the NF T 72-281 standard for its efficacy claims. Manufacturers of airborne disinfecting materials that base their efficacy claims on unsuitable EN standards provide inapplicable figures, which can potentially put a health threat to the user and the environment.

NF T tests and settings

NF T 72-281 is considered a "Phase 2, Step 2" assay conducted in a semi-field method. This means the disinfecting agent is tested as intended to use, and target microorganisms that are placed on a representative surface. Moreover, the test is carried out in a standardized test room, and the target samples are placed at a distance, facing away from the source of the disinfecting agent; for example, an ozone generator.

As for all microbiology tests, NF T 72-281 measures efficacy against a logarithmic scale. Microorganisms are counted as numbers of colony forming units (CFUs), and efficacy is given as the difference between the CFU count before and after application of the disinfecting agent. The result is given as a number of "log-reduction", where a log-reduction of 1 corresponds to a 10-fold reduction. For example, for a 10^6 initial CFU, a log-reduction of 4 would see a reduction to 10^2 CFU after treatment. This is typically marked on commercial packaging as a kill-rate percentage, where a log-2 reduction corresponds to a 99% germicidal power, a log-3 to 99.9%, and so forth.

NF T 72-281 is defined as a methodology for the "determination of bactericidal, fongicidal,

yeasticidal, mycobactericidal, tuberculicidal sporicidal and virucidal activity, including bacteriophages". The biocidal efficacy requirements depend on the target organisms:

- Bacteria: > 5-log reduction
- Spores: > 3-log reduction
- Fungi & yeasts: > 4-log reduction
- Viruses incl. phages: > 4-log reduction
- Mycobacteria: > 4-log reduction

Initial conditions require 1-log above the log-reduction objective (e.g., for bacteria, a load of 10^6 CFUs must be applied to the target surface).

Test microorganisms

Manufacturers are required to perform their efficacy tests on microorganism strains pre-approved by the NF T 72-281 standard. Those strains are representatives of the different target types (bacteria, spores, viruses, bacteriophages, mycobacteria, fungi and yeasts). Occasionally, more than one strain for a single target type is required, notably when variants exist (e.g. *P. aeruginosa, S. aureus, E. hirae* and *E. Coli* for bacteria, covering Gram-positive and Gram-negative strains).

Depending on the intended field of application of their disinfectant products, manufacturers can perform their tests on the entirety or part of those reference organisms. If additional target microorganisms are added to the methodology, proper documentation has to be provided covering the reason for their addition, the conditions at which they were grown and stored, and their general suitability for the NF T 72-281 standard. In addition to the entirety of the test microorganisms listed in NF T 72-281, STERISAFE also tests for additional target pathogens, selected for their relevance in particular applications (e.g. Vancomycin-resistant enterococci, VRE, for hospital disinfections). For the complete list of tested microorganisms, please refer to the Table in annex of the present document.

STERISAFE's vision

STERISAFE uses the NF T 72-281 standard for all its products, and as such can guarantee their efficacy. Considering the test conditions, the high kill-level objectives it requires, and its large target range, the NF T 72-281 should be the only acceptable standard methodology for efficacy claims of airborne disinfectant products. STERISAFE has been a pioneer in using this standard in industry of the ozone-based disinfection systems, and will continue to do so.

Reference

1. L'Association Française de Normalisation (2014). *NF T 72-281. Procédés de désinfection des surfaces par voie aérienne – détermination de l'activité bactéricide, fongicide, levuricide, mycobactéricide, tuberculocide sporicide et virucide incluant les bactériophages*. Paris: AFNOR

Annex: STERISAFE's NF T 72-281 results

Type (minimal log-reduction required)	Germ	STERISAFE log-reduction	% reduction
Bacteria (> 5.0)	*Enterococcus faecium**	6.73	99.99998%
	Enterococcus hirae*	**6.01**	**99.9999%**
	*Proteus mirabilis**	5.80	99.9998%
	Pseudomonas aeruginosa*	**6.99**	**99.99999%**
	Staphylococcus aureus*	**6.80**	**99.99998%**
	VRE*	5.51	99.9997%
	*Listeria monocytogenes**	≥ 7.70	99.999998%
	Escherichia coli*	**6.22**	**99.99994%**
Fungi & yeast (> 4.0)	***Candida albicans****	**4.17**	**99.993%**
Viruses (> 4.0)	**Adenovirus****	**≥ 4.25**	**99.994%**
	Murine norovirus (MNV)**	**≥ 4.96**	**99.999%**
	Modified Vaccinia Ankara (MVA)**	≥ 4.68	99.998%
	Polyomavirus SV40	4.77	99.998%
	Bovine coronavirus (BCoV)	≥ 4.75	99.998%
Mycobacteria (> 4.0)	***Mycobacterium terrae***	**4.42**	**99.996%**

In blue: Reference microorganisms listed in NF T 72-281

* Tested by Danish Technological Institute

** Tested by Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology