UNDERSTANDING EN 14885:2018

APPLICATION OF EUROPEAN STANDARDS FOR CHEMICAL DISINFECTANTS AND ANTISEPTICS

All disinfectants must undergo vigorous testing regimes before being put onto the market as stipulated by various governing bodies worldwide. EN 14885:2018 provides a framework for testing the activity of chemical disinfectants and antiseptics intended for use in human medicine, veterinary or food, industrial, domestic, and institutional areas for the European market. Standards within EN 14885:2018 may also be used to demonstrate efficacy in other countries where appropriate, for example, Australasia.

The purpose of EN 14885:2018 is to:

- ✓ enable the selection of appropriate standards by the disinfectant manufacturer in respect to the claims they wish to make.
- ✓ enable end-user assessment on the product information provided by the manufacturer.
- ✓ assist regulatory authorities in the assessment of claims made by the manufacturer for the product on the market.

The standards within EN 14885:2018 are categorised into different phases/steps of testing. Phases of relevance are:

- **Phase 2, step 1 tests (2,1):** these are quantitative suspension tests that establish a product's activity under simulated practical conditions.
- **Phase 2, step 2 tests (2,2):** these are quantitative laboratory tests that establish a product's activity when applied to inanimate surfaces or skin under simulated practical conditions (e.g. surface, insto-prument, handwash and hand rub tests).

The different phases of testing are used in combination to support efficacy claims for disinfectants.

The product efficacy claims are dependent on mandatory parameters such as *:

- **Microorganisms:** The microorganism species, chosen by scientists for testing under each regulatory standard within EN 14885:2018, are representative of the most resistant microorganisms to disinfectants in the medical area. Efficacy against these mandatory organisms infers efficacy against species of non-tested microorganisms, including emerging pathogens. For example, efficacy against mandatory viruses Poliovirus T1, Adenovirus T5 and Murine Norovirus in accordance with EN 14476:2013 + A2:2019 infers virucidal activity against other enveloped and non-enveloped viruses.
- **Contact Time:** The product contact time for each claim, is governed by the time it takes the product to inactivate or kill the mandatory microorganisms. However, the standards within EN 14885:2018 do stipulate expected efficacy contact times. Refer to table for specific norm contact time information.
- **Interfering Substance:** This refers to soiling conditions of surfaces expected within the field. Within the medical area, it is categorised as "clean conditions" (surfaces cleaned satisfactorily or are known to have minimal levels of organic and inorganic substances) or "dirty conditions" (surfaces known to or may contain organic and inorganic substances). This parameter is used to determine if a disinfectant claim regarding pre-cleaning (the removal of visible heavy soiling before disinfection) is necessary. I.e. If the product is tested in clean conditions only, then pre cleaning is necessary.
- **Log Reductions:** This is the reduction of the microorganism(s) stipulated [and any additional microorganisms tested]. A product which fails to meet these mandatory log reductions cannot make a claim against the specific activity tested for.

An activity claim will only be successful if testing against all mandatory requirements as per the respective standard is achieved with the required log reduction and within the contact times allowed.

* NB. Information above is specific to the medical area.

Read on to find out more.

TYPE OF ACTIVITY	SPORICIDAL	MYCOBACTERICIDAL / TUBERCULOCIDAL	VIRUCIDAL	FUNGICIDAL / YEASTICIDAL			BACTERICIDAL	
EN STANDARD	**EN 17126***	**EN 14348**	**EN 14476**	**EN 13624**	**EN 14562****	**EN 16615**	**EN 16615**	**EN 13727**
PHASE, STEP	2,1	2,1	2,1	2,1	2,2	2,2	2,2	2,1
REQUIRED MICROORGANISMS	*Bacillus cereus* *Bacillus subtilis*	*Mycobacterium avium* *Mycobacterium terrae*	Poliovirus type 1 Adenovirus type 5 Murine Norovirus (Full virucidal activity)	*Candida albicans* *Aspergillus brasiliensis*			*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae*	
			Adenovirus type 5 Murine Norovirus (Limited spectrum virucidal activity)					
		Mycobacterium terrae (Tuberculocidal activity only)	Vaccinia virus (Virucidal activity against enveloped viruses)	*Candida albicans* (Yeasticidal activity only)				
REQUIRED LOG_{10} REDUCTION	≥4					≥4 (f1) ≤50 cfu/25cm² (f2 to f4)	≥5 (f1)	≥5
CONTACT TIME	**≤ 15 mins for surfaces near patient and/or staff**	**≤ 5 mins for surfaces near patient and/or staff**						
	≤ 60 mins for other surfaces							

*EN 17126:2018 is the first standard for the evaluation of sporicidal activity in the medical area. Compliance with this new test norm is mandatory by June 2020 to make sporicidal activity claims.

**According to EN 14885:2018, where no specific activity in an area exists (i.e. no fungicidal activity test norm in the medical area for disinfectants used with mechanical action) another standard may be used.

Table 1. European regulatory compliance for surface disinfectants used in the medical area with mechanical action, adapted from BS EN 14885:2018 and the latest regulatory efficacy standards published.

Reference: Estonian Centre for Standardisation (EVS) (2018). EVS-EN 14885: 2018 - Chemical disinfectants and antiseptics- Application of European Standards for chemical disinfectants and antiseptics. European Committee for Standardisation.

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