European Norms (EN) for Testing of Disinfectants

Compared with any national standards the European Norms for Testing of Disinfectants mark a further step towards the greatest safety for the end-user when using disinfectants in practice.

What are Euro Standards?

Since 1990 common methods for Testing of Disinfectants have been being developed on the way to European Harmonization. In a first step pre-norms (preEN) are displayed. .By approval, the pre-norms are becoming European Norms (EN).[1] Due to continuous checking and constant improvement of methods the latest knowledge is incorporated.

In particular, it is of major importance to make uniform testings available for Medical Devices and Biocidal Products. In consequence, approved Euro-Norms will supersede national regulations . At the present time a variety of national regulations are valid. For instance in Germany the following regulations are active:

- Standard methods of the DGHM for Testing and Evaluation of Chemical Disinfectants issued: 1.9.2001
- Regulations for Testing of Viruses → Deutschen Vereinigung zur Bekämpfung von Viruskrankheiten [German Association for the Testing of Viruses] (DVV)
- Regulations for Testing → Robert Koch Institute (RKI)
- Regulations of the Deutsche Veterinärmedizinische Gesellschaft [German Veterinary Medical Association] (DVG)

The European Committee for Standardization, CEN, has inaugurated national and international working groups for employing consistent norms related to the following areas:

1) Human medicine
2) Veterinary medicine
3) Food, Industry, Household, Public Institutions

[1] Currently published Euro-Norms are listed in the annex.

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How are Euro-Norms being structured?

All Euro-Norms for all application fields are following the same principle:
All testings are divided into phases:

- Phase 1: Basic test
  - shows the in-principal antimicrobial efficacy of the related active
- Phase 2 / Step 1: Quantitative suspension test,
  - shows the efficacy under “close to practice” conditions in a test tube.
- Phase 2 / Step 2: Carrier test
  - shows the efficacy under “close to practice” conditions in a carrier test

In general, phase 2 tests are of particular interest to the end-users, showing relevance under practical conditions. Nevertheless, suspension tests are mandatory for display to the customers in order to ensure the optimum in safety and transparency. Depending on the area of application, the testings are being carried out with different loads. This is to simulate the different degrees of contamination with substances from the related environment. In principle there has to be a differentiation between testings under clean and dirty conditions.

How does the user benefit from Euro-Norms?

The end user profits from highest safety when using a disinfectant tested according to Euro-Norms.

- Close-to-practice testings
  - by testing close to daily use circumstances the user can rely with certainty on applying effective disinfectants
- Each testing is validated.
  - performance and results of any disinfectants can show reproducibility and repeatability for meeting highest quality standards
- New methods are being approved by ring tests.
  - evaluating new methods by more-than-two-eyes principle guarantees highest reliability in performance and results
- Continuous review of all norms (every 5 years)
  - Innovations and latest findings are being adapted

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- Consistent regulations for testing all over Europe
  - positive impact on transparency for comparing products on an international basis

World-wide, there are no other standards as specific, detailed, validated and reliable as the European Norms are. Neither going west – e.g. North America (no standards for viruses!!!) nor going east – e.g. Asia-Pacific (no specific norms ever developed) – will deliver standards of that meaningfulness. Hence, health care authorities world-wide are keen on introducing the idea of these norms to their health care systems.

Schülke & Mayr will give preference to Euro-Norms on the international basis.

Products having passed tests are allowed to label the specific EN-sticker.
When comparing products, pay particular attention to the concerned norms that are displayed.

A well tested product will have to pass all currently approved norms. (see annex)

Note: A manufacturer exhibiting only one or two basic tests e.g. EN 1040 / EN 1275) is allowed to print the specific label but the product does NOT meet the high standard requirements at the utmost level.

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Annex
List of norms

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Application of European Standards for Chemical Disinfectants and Antiseptics EN 14883						
			Health Care			Food, Pharma, Industry, Public Institutions
		Norm	Hands	Instruments	Surfaces	
Phase 1 (Basic test)						
Bac	suspension	1040	x	x	x	x
fung	suspension	1275	x	x	x	x
spores	suspension	14347	x	x	x	x
Phase 2, step 1						
bac	suspension	13727	x	x	x	
fung	suspension	13624	x	x	x	
bac	suspension	1276				x
fung	suspension	1650				x
myco	suspension	14348		x	x	
virus	suspension	13610				x
virus	suspension	14476	x	x	x	
spores	suspension	13704				x
Phase 2, step 2						
bac	carrier	1499	hyg,wash			x
bac	carrier	1500	hyg.disinf			x
bac	carrier	12791	surg.disinf			
bac	carrier	14561		x		
fung	carrier	14562		x		
myco	carrier	14563		x		
bac/fung	carrier	13697				x

Drafts				
viruses	carrier	WI 216037		x
spores	suspension	WI 216032		x

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