Tab 1

- ➢ **en 13697 requirements**
- ➢ **disinfectant validation**

Meta title : Factors That Influence EN 13697 Testing Outcomes

Meta description : Learn the key factors that influence EN 13697 testing outcomes, including contact time, surface type, temperature, organic load, and disinfectant formulation performance.

Slug:
factors-that-influence-en-13697-testing-outcomes

https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/efficacy-factors.html

Quick Insights

- EN 13697 is a phase 2, step 2 quantitative carrier test used to validate the efficacy of disinfectants on non- porous surface without mechanical action
- Products that are tested under EN 13797 include bactericidal, fungicidal, yeasticidal disinfectants used in non - medical settings
- Testing outcomes can change significantly based on contact time, organic load, surface type, temperature, and microbial strain selection.
- Products that perform well in suspension tests may fail EN 13697 because this method simulates real world usage conditions
- Understanding factors that can influence EN 13697 testing results help manufacturers to improve formulations, avoid retesting cost and delays in product launch

Summary

European standard EN 13697 is designed to evaluate bactericidal, fungicidal, and yeasticidal activity of disinfectants on non-porous surfaces without mechanical action. EN 13697 testing outcomes can be impacted by many factors such as contact time, organic load, disinfectant concentration, sampling and packaging errors, temperature, and formulation stability. Understanding these factors is helpful for manufacturers to improve product performance, reduce disinfectant validation failures, and generate reliable efficacy data for compliance and product performance claims.

What is EN 13697 testing?

EN 13697 is a phase 2, step 2 quantitative surface test developed to evaluate the bactericidal, fungicidal, and yeasticidal activity of chemical disinfectants used on hard, non-porous surfaces without mechanical action. EN 13697 standard stipulates the required log reduction criteria that needs to be achieved under standard testing conditions for a product to claim antimicrobial performance.

What kind of products require EN 13697 testing?

EN 13697 testing is commonly used in settings where disinfection is not medically indicated. This includes -

- Liquid disinfectants
- Sprays

Exception - Wipes are out of scope for EN 13698 testing

For disinfectant wipes testing, EN 16615 is the recommended standard.

Why EN 13697 is more challenging than suspension tests

In suspension tests, disinfectants are challenged with test microorganisms in a liquid medium, this enables quick interaction and results in good reduction in microorganisms.

1. Carrier (test) surface contamination

EN 13697 is more challenging than suspension tests because **carrier surfaces are deliberately contaminated** with test microorganisms and allowed to dry before disinfectant application. This results in -

- Dried inoculum strongly adhere to the surfaces and it becomes challenging to ensure disinfectants contact to all microbial cells
- Active ingredients may spread unevenly across the surface

2. Surface tension and product evaporation

Another major challenge is **disinfectant drying during the contact period**. On test surfaces, some formulations, especially alcohol-based products may evaporate quickly, reducing the actual exposure time available to kill microbes. Whereas, in suspension tests, this issue does not happen because the microorganisms and disinfectant mix well, allowing enough interaction.

3. No mechanical action during EN 13697 testing

EN 13697 also evaluates efficacy without mechanical wiping or scrubbing. The disinfectant must achieve the required log reduction entirely through chemical action on a dried contaminated surface, which makes passing criteria more difficult to achieve consistently.

Because of these real surface contamination conditions, products that easily pass suspension testing may still fail EN 13697 surface efficacy testing under the same concentration and contact time conditions.

For more details on EN 13697 testing, read our latest blog : EN 13697 : Disinfectant Testing for Non-Porous Surfaces

Also read - EN 1276 vs EN 13697: Which One Do You Need?

Main factors that Influence EN 13697 testing outcomes

The outcome of an EN 13697 test is not influenced only by the disinfectant formulation itself but also how the samples are handled while shipping and during laboratory testing.

1. Sending non final or development stage samples

One of the most common factors is submitting an initial or development phase sample instead of the final commercial formulation for testing. Sending early stage formulations can lead to false interpretation of product efficacy. If such samples are tested, the results may not represent the actual final product performance.

It is important to ensure that manufacturers should only send finalized and production ready batches for EN 13697 testing.

2. Improper packaging and transportation of samples

Incorrect or poorly sealed packaging can compromise product integrity before it even reaches the antimicrobial testing laboratory. Major mistakes include leakage, exposure to heat, sunlight, moisture, or air during transportation can impact antimicrobial efficacy of disinfectants and also make it more susceptible to microbial contamination.

3. Sample Contamination during handling

If samples are not properly handled, contamination can occur before and during laboratory testing. External contamination by microorganisms, use of non-sterile containers or incorrect transfer techniques can interfere with the actual efficacy results

Even a disinfectant product with strong antimicrobial efficacy can show poor performance if it is mishandled.

4. Incomplete details about product

Product details include recommended dilution, contact time, active ingredient concentration, intended use conditions, or storage instructions. Missing or incorrect details shared with the testing lab can lead to testing under uncertain conditions that do not match the product's real use application.

5. Possible laboratory errors impacting EN 13697 testing results

Laboratories use validated protocols, but operational errors may still affect testing results if procedures are not handled and executed correctly.

Possible issues related to the lab could be:

- **Incorrect dilution preparation**

Disinfectants must be prepared exactly at the recommended use concentration before testing. Incorrect measurements, calculation mistakes, improper mixing, or dilution can alter antimicrobial performance, eventually leading to inaccurate efficacy results.

- **Errors in microbial inoculum concentration**

EN 13697 requires standardized microbial concentrations for reliable testing. If the inoculum levels are too high, the disinfectant may face an excessive microbial challenge. If it is too low, the product may appear more effective than it actually is.

- **Inadequate neutralization after contact time**

After the required contact time, the disinfectant must be completely neutralized to stop further antimicrobial activity. Incomplete neutralization may allow the disinfectant to continue killing microorganisms during recovery, resulting in false positive efficacy data.

- **Incorrect contact times**

EN 13697 testing demands strict control of contact time, drying conditions and temperature. Small variations can influence microbial survival and antimicrobial performance of disinfectant products which can give wrong testing outcomes.

- **Log reduction calculation errors**

EN 13697 test result date heavily depends on accurate colony counting and correct log reduction calculations. Errors in dilution factors, microbial enumeration, or data interpretation can lead to wrong interpretation of product efficacy

Importance of understanding influencing factors before regulatory testing

Understanding the factors that influence EN 13697 outcomes is essential before preparing performance efficacy data to support performance claims and regulatory claims. It is important to understand that disinfectant products don't fail the testing due the lack of antimicrobial potential, but if testing parameters are not properly optimized beforehand. Issues such as incorrect contact time, inadequate neutralization, instability under dirty conditions, or improper product dilution can significantly impact results.

Mechanical Action vs Non-Mechanical Action

Why EN 13697 focuses on non-mechanical action

As per EN 13697 testing guidelines, efficacy of disinfectants is done without wiping, scrubbing, or mechanical action. This is done to measure the intrinsic chemical efficacy of the disinfectant itself.

When EN 16615 is more appropriate

EN 16615 is more suitable for disinfectant wipes or products designed for mechanical surface cleaning because it includes wiping action during efficacy evaluation.

How Manufacturers Can improve EN 13697 Performance

➢ **Optimize product concentration**

Manufacturers should determine the minimum effective concentration required to consistently achieve target log reductions.

➢ **Validate contact time claims**

Products claiming rapid disinfection should undergo validation at the exact intended contact time.

➢ **Test under both clean and dirty conditions**

Evaluating performance under multiple contamination conditions helps ensure broader real-world reliability.

➢ **Conduct pre-screening studies**

Preliminary internal testing can identify formulation weaknesses before formal regulatory evaluation.

Importance of accurate log reduction measurement

Accurate log reduction measurement is one of the most critical components of EN 13697 testing because the final efficacy claim of a disinfectant depends entirely on how effectively surviving microorganisms are recovered and quantified after challenging the product with a test sample.

In EN 13697, disinfectant performance is expressed as a logarithmic reduction in the number of viable microorganisms present before and after disinfectant exposure.

EN 13697 test requirements : Required passing criteria

To meet EN 13697 efficacy requirements, disinfectants generally must achieve:

- ≥4 log reduction for bactericidal activity

- ≥3 log reduction for fungicidal and yeasticidal activity.

Choosing the right laboratory for EN 13697 testing

Selecting the right laboratory is critical for generating reliable EN 13697 efficacy data that can withstand regulatory submissions and support strong antimicrobial claims. At Microbe Investigations Switzerland (MIS), our experts help manufacturers evaluate disinfectant performance under standardized test conditions using customized testing solutions tailored to your product application.

For more details on EN 13697 test requirements or any other questions on disinfectant validation, contact our experts now.

Similar blogs -

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- https://microbe-investigations.com/blog/comparing-en-1276-and-en-1040-choosing-the-best-standard-for-antibacterial-disinfectant-test/
- https://microbe-investigations.com/blog/difference-between-british-standards-en-1276-vs-en-14476/

FAQs

What factors most commonly affect EN 13697 results?

Factors such as contact time, disinfectant concentration, organic load, microorganism type, temperature, and surface material can significantly influence EN 13697 outcomes.

Does temperature affect disinfectant performance in EN 13697?

Yes. Low temperatures can slow disinfectant activity and reduce microbial kill efficiency, especially for certain chemical formulations.

Why is neutralization important in EN 13697 testing?

Neutralization is performed to stop disinfectant activity after the required contact time and prevents misleading testing results.

Can the same disinfectant perform differently on different surfaces?

Yes. Test surface properties such as texture, residue retention, and drying behavior can influence disinfectant spreading and microbial contact.

What is the role of interfering substances in EN 13697?

Interfering substances simulate real-world contamination conditions and help evaluate disinfectant efficacy under clean and dirty environments.

Why are dried surface tests more difficult than suspension tests?

Microorganisms attached to dried surfaces are harder to eliminate because disinfectant penetration and surface contact become less uniform.

How does water hardness affect disinfectant efficacy?

Minerals in hard water may interact with active ingredients and reduce the antimicrobial performance of certain disinfectants.

What microorganisms are mandatory in EN 13697?

EN 13697 commonly includes bacterial, yeast, and fungal organisms such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Candida albicans*.

Can EN 13697 testing be customized for additional organisms?

Yes. Additional microorganisms can be included depending on product claims, industry requirements, or targeted applications.

Does EN 13697 include mechanical wiping action?

No. EN 13697 evaluates disinfectant efficacy without wiping or scrubbing to measure chemical action alone.

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