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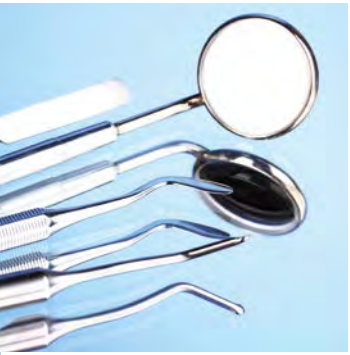
IHO INDUSTRIAL ASSOCIATION HYGIENE & SURFACE PROTECTION

Disinfection done correctly

Basic knowledge edition



HC HEALTHCARE

KC KITCHEN & CATERING

BC BUILDING CARE

IL INDUSTRIAL LAUNDRY

FBA FOOD, BEVERAGE & AGRICULTURE

Contents

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Part 1: Targeted and efficient use of disinfectants

The aim of disinfection measures is to contain the spread of pathogens and thus prevent the spread of infections. The German Pharmacopoeia defines disinfection as: putting dead or living material in a state that it can no longer infect. Important measures in the context of chemical disinfection are the disinfection of hands, surfaces, equipment, accessories and instruments. The various measures to be taken depend on the environment or facility and the expected contamination. A distinction is made between disinfection (germ reduction, e.g. 10^{-5} depending on the requirements of the test standard) and sterilisation (removal or killing of all microorganisms with a maximum residual content of 10^{-6}).

1. What is the spectrum of activity?

"Spectrum of activity" describes the efficacy against the individual micro-organisms and can be found on the label and product data sheet of the disinfection products.

When selecting a suitable disinfectant, the user must take into account the disinfectant's spectrum of activity.

Depending on the intended application and the expected contamination in the respective environment, different spectra of activity are required.

Overview of the spectra of activity

The terms used to characterise the impact spectra are explained below:

Bactericide
Describes the efficacy against vegetative bacteria, e.g. Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, but also against multi-resistant pathogens such as MRSA.

Tuberculocide
Describes the efficacy against the tuberculosis pathogen: Myco-bacterium tuberculosis.

Yeasticide
Describes the efficacy against yeasts, e.g. Candida albicans.

Mycobactericide
Describes the efficacy against the tuberculosis pathogen and atypical mycobacteria, e.g. Mycobacterium avium.

Sporicides
Describes the efficacy against spores of spore-forming bacteria such as Clostridioides difficile.

Other agents, e.g. against mammals, birds, insects or plants, do not fall under the term disinfectants considered here. Cosmetic soaps that may carry secondary disinfectant claims are not considered, as these products are not regulated as medicinal or biocidal products.

Fungicide

Describes the efficacy against yeasts and moulds, e.g. Candida albicans and Aspergillus brasiliensis.

Limited virucidal activity

Describes the efficacy against all enveloped viruses, e.g. hepatitis B virus (HBV), hepatitis C virus (HCV), influenza viruses, human immunodeficiency virus (HIV), corona viruses.

Limited virucidal activity PLUS

Describes the efficacy against all enveloped viruses and additionally the efficacy against the non-enveloped adenoviruses, rota viruses and noroviruses. These non-enveloped viruses cause the most frequent outbreaks. They are more stable than enveloped viruses and therefore more difficult to inactivate, but not as stable as other non-enveloped viruses.

Virucide

Describes the efficacy against all enveloped and non-enveloped viruses; non-enveloped viruses include noroviruses, rota viruses, adenoviruses, hepatitis A viruses (HAV), polio and panoviruses.

2. Which spectrum of activity for which case?

2.1. Routine disinfection / prophylactic disinfection

The purpose of routine disinfection (also known as preventive disinfection, ongoing disinfection, prophylactic disinfection) is to limit the spread of pathogens or potential pathogens and extends to surfaces that can be assumed to have been contaminated with pathogen-containing material without this being recognisable or visible in individual cases.

When selecting a suitable disinfectant for routine use, several aspects must be taken into account. On the one hand, the required spectrum of efficacy must be achieved under application conditions that are as close as possible to those found in practice. On the other hand, users and materials should not be exposed to any negative influences from the disinfectant.

Firstly, the required spectrum of activity for the intended application must be determined and specified. This is essentially based on the intended application and the pathogenic microorganisms and / or spoilage organisms to be expected there and is carried out as follows usually as part of a risk assessment.

Disinfectants for routine disinfection should be at least bactericidal and yeasticidal.

There are various aids available to the user for selecting a suitable disinfectant:

Product data sheets from the manufacturers provide information on the spectrum of activity, application concentrations and exposure times of the relevant products.

Safety data sheets contain information on the safe handling of the products (note: the information usually only refers to the concentrate and not to the diluted application solution).

It is important that the application conditions specified by the manufacturer (concentration, exposure time, etc.) are always observed!

2.2. Targeted disinfection

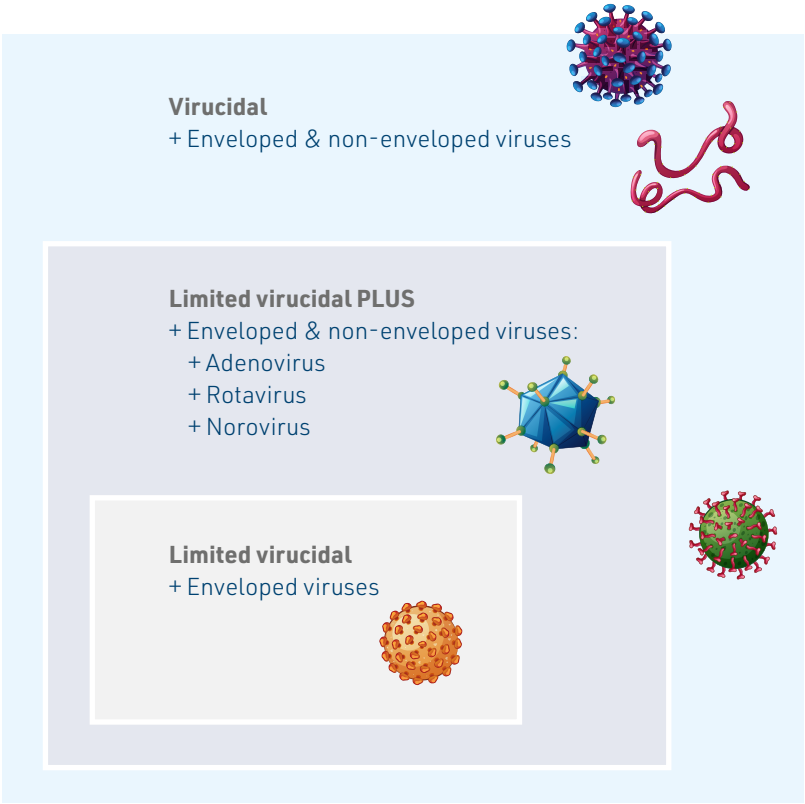
Targeted disinfection measures are carried out:

+ if there is recognisable contamination of surfaces, e.g. by blood, pus, excretions or other bodily fluids;
+ during final disinfection in areas or rooms used for the care or treatment of a patient infected or colonised with specific pathogens. This disinfection is intended to prepare the room / area so that it can be used for the care and treatment of another patient without risk of infection;
+ in outbreak situations and when special, e.g. multi-resistant or highly infectious pathogens (e.g. MRSA, ESBL, noroviruses, rotaviruses, Clostridioides difficile) occur.

When disinfecting in the presence of specific pathogens, the required spectrum of activity depends on the type of pathogen:

If non-enveloped viruses occur, disinfectants should also be effective against non-enveloped viruses in addition to their bactericidal, yeasticidal and limited virucidal efficacy.

The noroviruses, rota viruses and adenoviruses, which are frequently responsible for outbreaks, are inactivated with disinfectants with the limited virucidal PLUS spectrum of activity. There are also other non-enveloped viruses, such as hepatitis A viruses, whose transmission can be prevented by using products with the virucidal spectrum of activity.



The highest level of effectiveness against viruses is virucidal, followed by limited virucidal PLUS and limited virucidal.

Disinfection in the event of bacterial spore formers (e.g. Clostridioides difficile)

Disinfectants should also be effective against bacterial spore formers (sporicidal or sporicidal against C. difficile).

Disinfection in the event of tuberculosis pathogens (e.g. Mycobacterium tuberculosis)

Disinfectants should also be effective against the tuberculosis pathogen (tuberculocidal).

Disinfection in the event of mycobacteria (e.g. Mycobacterium avium)

Disinfectants should also be effective against atypical mycobacteria (mycobactericidal).

Examples of frequently asked questions:

Do I need a special disinfectant against multi-resistant pathogens such as MRSA, MRGN and VRE?

MRSA, MRGN and VRE are bacteria. A bactericidal disinfectant is therefore sufficient.

Do I need a special disinfectant against influenza viruses?

Influenza pathogens are enveloped viruses. A limited virucidal disinfectant is therefore sufficient.

Do I need a special disinfectant against coronaviruses such as SARS-CoV-2?

Corona viruses are enveloped viruses. A limited virucidal disinfectant is therefore sufficient.

3. What are the legal requirements regarding disinfection in the EU?

All areas of application in which disinfectants are (or must be) used require facility-specific hygiene management that includes disinfection measures. These requirements are laid down in various laws, regulations and recommendations.

The most important legal framework conditions for disinfection in the EU are explained on the following pages.

Important guidelines and recommendations are

+ Guidelines for hospital hygiene and infection prevention
+ Hand hygiene
+ Hygiene requirements for cleaning and disinfecting surfaces
+ Hygiene requirements for the reprocessing of medical devices
+ Infection prevention in care homes

In addition to national regulations, European regulations and directives also apply in the food production environment. European Directive 93/43/EEC on the hygiene of foodstuffs lays down general hygiene regulations and regulates the verification of compliance with these regulations. In addition to this general basis, specific hygiene regulations are required for certain foods. These regulations are laid down in the European regulation on food hygiene (EC852/2004).

The HACCP system (Hazard Analysis Critical Control Points) is the standard in food processing environments such as the catering industry, which essentially regulates the implementation of preventative cleaning and disinfection measures via internal control mechanisms.

3.1. Biocidal Products Regulation (BPR) EU 528/2012

The BPR regulates the supply of disinfectants on the European market.

+ In the BPR, manufacturers of biocidal active substances are obliged to provide comprehensive data to determine the effects of the use of biocidal active substances, e.g. on consumers and the environment. This procedure then leads to the authorisation or non-authorisation of an active substance in the EU.
+ Following the authorisation of an active ingredient, the formulators of disinfectants are also subject to extensive obligations to provide evidence in order to obtain or, in the case of existing products, to maintain their availability on the market.
+ Existing active substances have been successively evaluated in the BPR since 2012, which currently (2024) results in a mix of national and European rules for disinfectants, depending on the active substances they contain.
+ The BPR stipulates that formulators can only use active substances from manufacturers that are on the Article 95 list of the BPR. Access is granted to those active substance manufacturers whose raw material specifications match the data submitted in the active substance approval procedure.

3.2. Medical Devices Regulation (MDR) EU 2017/745

The MDR is the legal framework for medical devices law in the EU. European medical device law is based on the global concept of conformity assessment. Medical devices are not approved by the state, such as medicinal products, but are subject to the technical harmonisation directives on the placing on the market of technical industrial products. Conformity assessment procedures are carried out depending on the risk classification with the involvement of a notified body.

The purpose and objective of the regulation is to create harmonised European medical device legislation to ensure the availability of safe medical devices and rapid market access, combined with balanced control before and after market launch.

Part 2: Disinfectant tests

The effectiveness of disinfectants is tested as part of the authorisation process in accordance with European test methods (set out in the relevant EN standards). As a rule, these are harmonised with national standards.

In many areas, disinfection products are biocidal products and are subject to EU Regulation 528/2012 (Biocidal Products Regulation). The reprocessing of medical devices – a specialised area in the healthcare sector – is carried out with disinfectants that are subject to the EU Medical Devices Regulation 2017/745. What both regulations have in common is that they represent a binding legal act that all EU countries must implement in full.

The proofs of efficacy are part of the product authorisation documents, such as the biocidal product dossier, which every manufacturer must submit to the relevant national authority for review.

In Germany for example, there is the special situation that hand disinfectants can also be authorised as medicinal products for historical reasons. These authorisations are mostly secured by the protection of existing authorisations. New products fall under the Biocidal Products Regulation and can no longer be authorised as medicinal products.

There are very few areas in which European harmonisation is not yet so advanced. This is the case, for example, in the veterinary sector when it comes to determining the effectiveness of disinfectants against parasites or viruses.

In order to help users select suitable products in Germany, for example, various lists (by the IHO, VAH or DVG) have been established in which disinfectants tested for efficacy are compiled for specific areas of application. These lists are market overviews that are not legally binding in themselves.

The following pages describe the principles of the tests.

1. How is the effectiveness of disinfectants tested in Europe?

The testing of disinfectants for their effectiveness is not a single test, but a combination of several test procedures that are built on each other.

At European level, a distinction is made between several phases of the audit:

Phase 1: Basic tests
No consideration of the subsequent use of the disinfectant product, therefore implementation not mandatory for disinfectants.

Phase 2/Stage 1: quantitative suspension test
Consideration of application conditions (temperature, load, time)

Phase 2/Stage 2: practical germ carrier tests
A realistic application on the surface is simulated and tested.

Phase 3: Practical and field trials
Not yet finalised.

The standard EN 14885 "Chemical disinfectants and antiseptics – Application of European standards for chemical disinfectants and antiseptics" describes in detail which test is required for which application. The standard is continuously updated, as new standards for testing disinfectants are constantly being added or revised.

The test methods differ with regard to the subsequent area of application:
+ Medical area
+ Animal husbandry
+ Food sector and public facilities

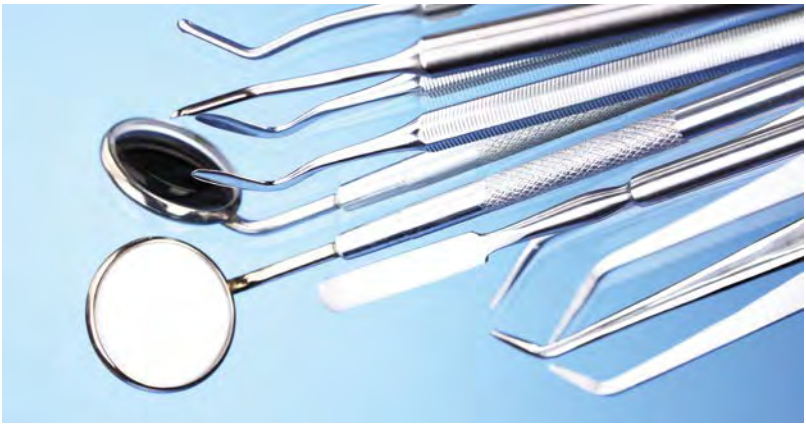
Within the "Medical use" area, the specific application of the disinfectant is taken into account in the test methods.

There are test methods for the

+ Skin and hand disinfection
+ Surface disinfection
+ Disinfection of instruments
+ Disinfection of laundry

Harmonised European methods are preferably used for efficacy testing. In a few exceptional cases, national methods may also be used, such as for example in Germany those of the German Association for Applied Hygiene (VAH) or those of the DVV (Deutsche Vereinigung zur Bekämpfung von Viruskrankheiten e.V.) and the RKI (Robert Koch Institute) specifically for the detection of virucidal efficacy.

These methods for testing disinfectants for the healthcare sector are divided into different phases and areas of application, just like the methods at European level. For example, if European methods already exist, the VAH methods are harmonised with these in order to meet the European standards. Only if there is not yet an internationally recognised method for a specific proof of efficacy does the national method have sole validity.



The IHO is a member of the European network of national associations, manufacturers and suppliers of cleaning, maintenance and disinfectants A.I.S.E.

At a glance

+ The authorisation of biocidal products and the proof of efficacy required for this are carried out in accordance with EU law and take precedence over national regulations.
+ Medical devices are regulated under European medical devices legislation.
+ Proof of the microbiocidal efficacy of disinfectants must be provided on the basis of internationally recognised methods/ EN standards.
+ The only exception is if there are no harmonised EN methods for the intended area of application (for example an epidemic).

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Part 1

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+ In the IHO – Industrial Association for Hygiene and Surface Protection for Industrial and Institutional Applications e.V., the manufacturers of professional cleaning agents and disinfectants are organised.
+ Since 1992, the association has represented mainly small and medium-sized companies in an industry that is of great importance to society, for example in consumer protection, due to its services in the field of cleaning, disinfection and care in professional applications.
+ The products and services of the member companies are used in a wide variety of areas to ensure hygiene, care and protection of people, animals and assets.
+ With its bundled expertise, the association is the competent point of contact for the specialised public, industry, authorities, politics, etc.

Find out about the many other tasks and fields of activity of our association at: **iho.de**.

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