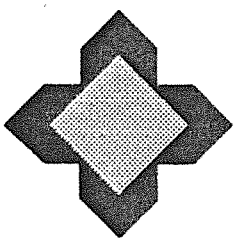
THE KLORSEPT ADVANTAGE

IN

INFECTION CONTROL



Medentech Ltd.
Whitemill Industrial Estate
Whitemill Road
Wexford, Ireland

Tel: Intl. + 353 53 41866/41842/41809
Fax: Intl. + 353 53 41271

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While antimicrobial agents have been considered the "wonder drugs" of the 20th century, clinicians and researchers are now acutely aware that microbial resistance to drugs has become a major clinical problem ..... A variety of solutions have been proposed. The pharmaceutical industry is attempting to develop new agents that are less susceptible to current resistance mechanisms. Unfortunately, the organisms appear to rapidly develop new resistance mechanisms ..... In the inpatient setting, ***strict adherence to infection control procedures is essential.*** *Health care workers need to understand that antimicrobial resistance is an accelerating problem in all practice settings that can directly compromise patient outcomes.*

Michael D. Katz. Clinical Research News for Arizona Physicians, 9, September 1994 (University of Arizona Health Services Center, Office of Public Affairs).

CONTENTS

1.0 INTRODUCTION

The Need for Infection Control Programmes

A successful infection control programme consists of many interrelated components that contribute to the health and well being of patients and staff in the medical environment.

The programme should be based on practical, scientifically-sound and socially acceptable procedures and materials, for prevention of cross infections. There are two basic reasons for implementing infection control programmes in the hospital, dental and medical environments.

Firstly, there is the obvious ethical duty to minimise the risks to patients and staff from infection, including nosocomial infections (that is, hospital-acquired infections). Generally speaking, patients are more susceptible to infection than the general population. This can be due to an existing illness, to immunosuppressive treatment, or to medical and surgical procedures. Hospital patients are particularly prone to infection, which can threaten the success of their treatment, or even their lives. Additionally, patients admitted with existing infections can be in direct contact with other susceptible patients, or they can be indirectly in contact through sharing the same nursing staff and doctors. Furthermore, the high use of antibiotics in medical treatment centres favours the emergence of resistant strains of bacteria, which can lead towards the transmission of more virulent strains to patients and staff. It is of paramount importance to control the environmental spread of infection from these strains.

Secondly, infections are costly to health authorities. Nosocomial infection will increase the treatment costs and number of bed days occupied by a patient (bed days that are then not available to the next patient on the waiting list). The cost effectiveness of an infection programme is difficult to assess, but the necessity and success of a rational programme was proven by an American Study on the Efficacy of Nosocomial Infection Control (SENIC) (1). This project compared the frequency of infection of 500 deliberately selected patients in the years 1970 and 1976, in 338 randomly chosen clinics, which greatly differed in hospital hygienic surveillance. The evaluation of data from 338,000 patients who stayed more than 3.5 million days in hospital clearly demonstrated the effectiveness of infection control in reducing the rates of infections in hospitals. The project demonstrated that whilst the infection rate rose by 18% in the clinics without infection control, in the same period the infection rate decreased by 32% in the clinics with infection control programmes.

An infection control programme should be both ethically beneficial and cost effective. The programme should be considered as part of an overall policy for achieving good quality care for patients.

Sterilization and disinfection procedures are integral parts of any infection control programme to assure a safe environment for staff and patients. These procedures are discussed in the remainder of this report.

2.0 STERILIZATION AND DISINFECTION

Sterilisation is the complete elimination or destruction of all forms of microbial life.

High-level disinfection describes a process of destroying all microorganisms, with the exception of high numbers of bacterial spores.

Intermediate-level disinfection inactivates Mycobacteria, vegetative bacteria, viruses, fungi, but not necessarily bacterial spores.

Low-level disinfection will kill bacteria, some viruses and fungi, but cannot be relied upon to kill resistant micro-organisms such as tubercule bacilli or bacterial spores.

Sterilization and disinfection are terms used to describe activity on inanimate objects.

Sterilisation

Items that require sterilization are critical items that enter tissue or vascular systems, or where blood flows through them, eg surgical instruments, cardiac and urinary catheters, implants, needles etc.

Disinfection

Disinfectants are used in infection control programmes for three principle purposes:

i) to render contaminated objects safe for further use.
ii) to reduce or remove pathogenic microbial organisms from environmental surfaces.
iii) to prevent the spread of infection from microorganisms by contaminated wastes.

High-level disinfection is used for semicritical items that come into contact with mucous membranes or non-intact skin (eg respiratory therapy and anaesthesia equipment, endoscopes etc) and high risk areas (eg operating theatres, intensive care, post-mortem rooms, clinical laboratories etc). Disinfectants require sporicidal activity.

Intermediate-level disinfection is used for some semicritical items (eg oral and rectal thermometers, bedpans etc) and for medium risk areas (eg patient areas, diagnostic rooms, sterile supplies etc). Disinfectants require tuberculocidal activity.

Low-level disinfection is used for non-critical items used on contact with skin (eg crutches, bed rails, stethoscopes, crockery etc) and low risk areas (eg administration, cafeteria, kitchens and other non-patient areas).

When considering the disinfection activity required to prevent the environmental spread of infection, the following guidelines are suggested:

See following page .....

Area of Use	Microbicidal Activity Required				
	Sporicidal	**Tuberculocidal**	**Virucidal**	**Fungicidal**	**Bactericidal**
High-risk areas eg operating theatres, post mortem rooms, intensive care, isolation units, laboratories. Pathology and laboratory wastes.	✓	✓	✓	✓	✓
Medium-risk areas, eg Patient areas, diagnostic rooms, sterile supplies.	-	✓	✓	✓	✓
Low-risk areas. eg non-patient areas, kitchens, cafeteria, administration, trolleys etc.	-	-	-	-	✓

There are several key factors to consider when choosing an appropriate disinfectant:

- it should have a demonstrable broad spectrum of activity, appropriate for it's intended use.
- it should have rapid activity for surface disinfection.
- as far as possible, it should be compatible with environmental factors, eg soap, water hardness, organic matter, plastics, stainless steel etc.
- it should be non-toxic, non-irritating and non-corrosive at in-use dilution.
- it should be stable.
- the cost of in-use dilutions should be inexpensive.
- correct dilutions should be easily understood and achieved.
- storage and handling should be simple and cost effective, eliminating the need for professional intervention, weighing/measuring, special diluents etc.

It should be noted that different disinfectants are not always interchangeable. Use of inappropriate disinfectants or in-use dilutions may lead to excessive costs.

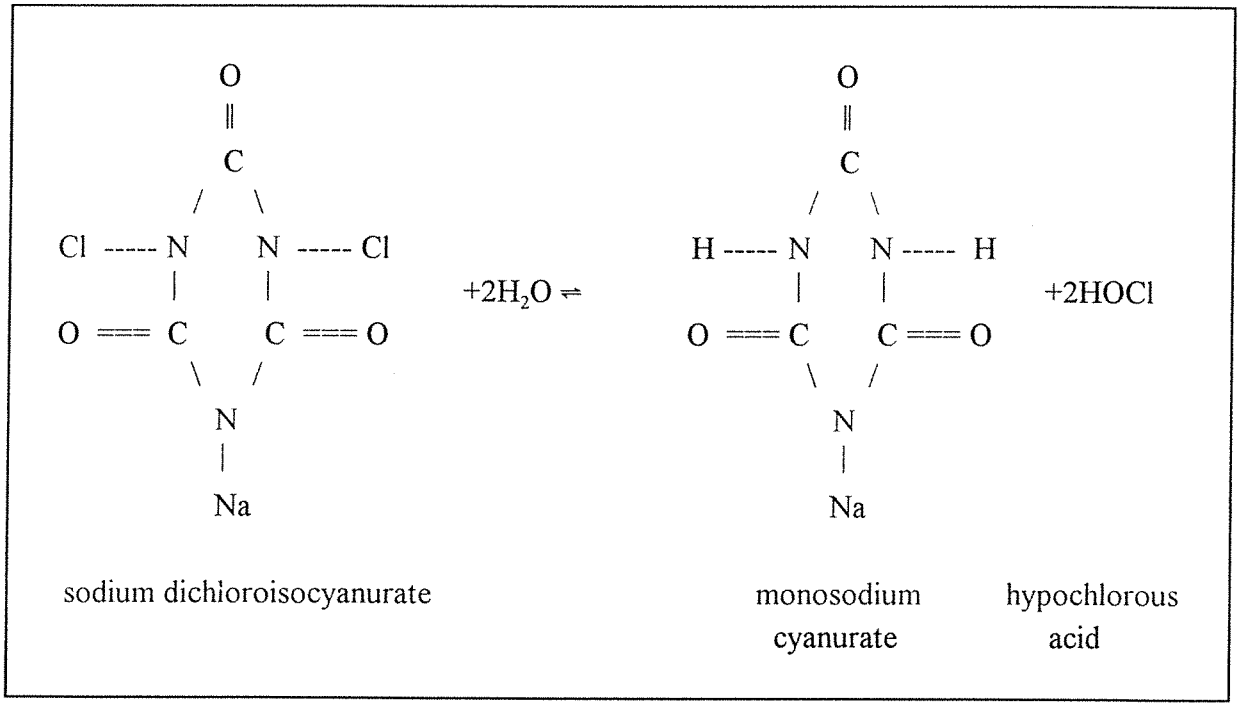
3.0 KLORSEPT AND KLOR-KLEEN

Klorsept and Klor-Kleen are environmental disinfectants, for use at all levels (they are not recommended for prolonged immersion of metallic items or instruments). Klorsept is presented in the form of effervescent tablets which, when added to water, give disinfectant solutions of known and accurate strengths. Klor-Kleen has the same formulation with the addition of a compatible detergent.

The active ingredient in these products is sodium dichloroisocyanurate (also known as NaDCC, sodium troclosene and sodium dichloro-s-triazine trione).

3.1 Chemistry of NaDCC

NaDCC is the sodium salt of 1,3 - dichloro - 1,3,5 - triazine - 2,4,6 (1H,3H,5H) - trione and contains about 62% 'available chlorine'. On dispersal in water, hypochlorous acid (the active compound) and monosodium cyanurate (a non-toxic compound) are very quickly liberated:



It is generally considered that the lethal biocidal action on organisms is due to chlorination of cell protein or enzyme systems by undissociated hypochlorous acid, causing hydrolysis of peptidic chains of cellular membranes of pathogenic germs.

3.2 Comparison of NaDCC and other Chlorine Donors

Although hypochlorous acid is the biocidal component released with other chlorine disinfectants (eg sodium hypochlorite, calcium hypochlorite), the activity and biocidal capacity of NaDCC is far superior, principally due to two factors.

Firstly, NaDCC produces acidic solutions, unlike other chlorine products, such as sodium hypochlorite (bleach), which produce alkaline solutions. Now HOCl dissociates according to the

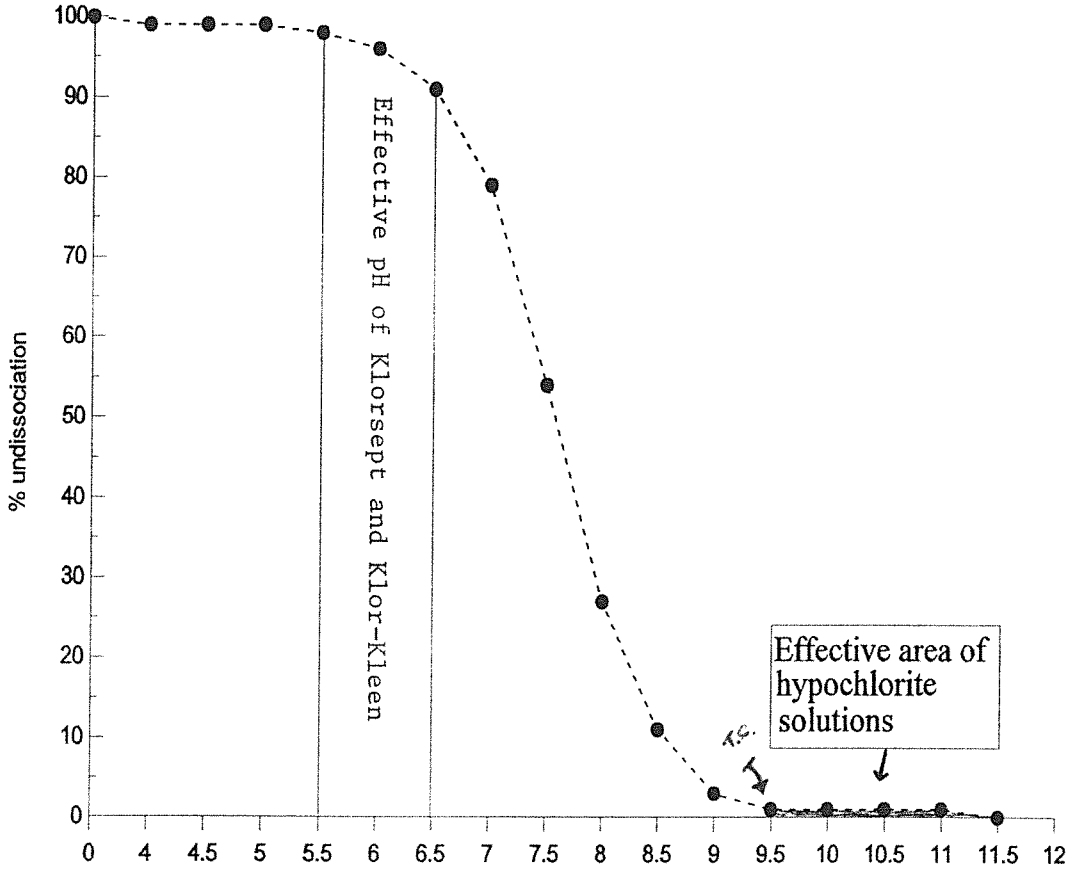
alkalinity or acidity (pH) of the solution, thus:

$$HOCl \rightleftharpoons OCl^- + H^+$$

HOCl and OCl^- (hypochlorite ion) represent the free available chlorine measured in solution and usually expressed in mgs per litre (or parts per million - ppm). However, OCl^- only has one hundredth of the potency of undissociated HOCl and, therefore, has far less biocidal activity. This dissociation is pH dependent:

	pH	% HOCl (@ 20°C)
ACID	5.0	99.740
	5.5	99.180
	6.0	97.450
	6.5	92.370
Neutral (pure water)	7.0	79.290
ALKALINE	7.5	54.770
	8.0	27.690
	8.5	10.800
	9.0	3.690
	9.5	1.190
	10.0	0.380
	10.5	0.120
	11.0	0.040
	11.5	0.012

Now, the inorganic hypochlorites have pH's that are very alkaline, being greater than pH 9.5, whereas Klorsept and Klor-Kleen produce solutions of pH 5.5 to 6.5. So that they release free available chlorine with over 90% of undissociated HOCl, whereas the inorganic hypochlorites release the free available chlorine with less than 10% undissociated HOCl:



Secondly, only 50% of the total available chlorine is 'free' with Klorsept and Klor-Kleen, the rest is 'combined' in the form of mono or dichloroisocyanurates. The equilibrium between 'free' and 'combined' chlorine remains stable until there is a chlorine demand on the solution from microorganisms, organic or nitrogenous material, which displaces the hypochlorous acid. This disturbs the chemical equilibrium, releasing further hypochlorous acid to rapidly replace that used in satisfying the chlorine demand. This process continues until no more 'free' chlorine is available. This whole equilibrium provides for the self-regulating, progressive release of 'free' chlorine found with these products, giving the improved efficiency and safety in use when compared to other chlorine agents.

This release of 'latent' chlorine provides for the greater biocidal capacities found with NaDCC when compared to inorganic hypochlorites and explains why NaDCC is less inactivated in the presence of organic matter. It may also explain why NaDCC solutions are less corrosive and less toxic (2).

Many studies confirm the superior biocidal activity of NaDCC.

3.3 Comparative Biocidal Activities of NaDCC and Sodium Hypochlorite (NaOCl)

Bacteria and Fungi

In one study (3) the activity of an NaDCC solution was compared with a hypochlorite solution containing an equivalent concentration of available chlorine (125ppm) against a strain of ***Escherichia coli***. Although both formulations were effective, the NaDCC had the capacity to effect a kill of at least twice as many organisms as the hypochlorite formulation, ie the NaDCC solution at half strength (62.5ppm) retained a bactericidal capacity equal to that of the hypochlorite at the full strength. There was also a marked difference in the extent to which the two formulations were affected in the presence of milk. 1% milk was sufficient to reduce the bactericidal capacity of the hypochlorite to less than 10^6 organisms per ml, whilst 2% rendered the product virtually inactive. The NaDCC retained a bactericidal capacity greater than 10^8 organisms per ml even in the presence of 2% milk.

In a further study (4), the disinfection capacities of both NaDCC and NaOCl formulations at 'in use' concentrations containing 125ppm available chlorine against the bacterial species ***Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*** and ***Klebsiella aerogenes***, and the fungal species ***Candida albicans***. For all bacterial species the disinfection capacities were greater than 10^9 organisms per ml and for ***C. albicans*** greater than 10^7 organisms per ml. In order to obtain an accurate estimate of the 'extinction zone' using the same inoculum size for both NaDCC and NaOCl formulations, capacity tests were also carried out using NaDCC at 50% of the 'in use' dilution. Both formulations showed a high disinfection capacity but, as with ***E. coli*** tested perviously, NaDCC showed significantly higher activity against bacterial species, with no significant difference against ***C. albicans.***

In a more recent study (5) a comparison was made between NaDCC and NaOCl solutions against ***Pseudomonas aeruginosa*** in the presence of horse serum. The degree of inactivation with various concentrations of horse serum was quantified and expressed in terms of a neutralization coefficient. NaDCC solutions were demonstrably less prone to inactivation than NaOCl solutions, with the disparity diverging as the serum concentration increased. In 30% serum an NaDCC solution containing 4,000ppm available chlorine exhibited similar bactericidal activity to an NaOCl solution containing 17,000ppm available chlorine. This better capacity of NaDCC has particular significance where the organic contamination is blood, where the disparity can be expected to be even greater due to its expectancy to cause more inactivation than serum.

Spores

Further investigations (6) supported this earlier work demonstrating superior activity of NaDCC over NaOCl, in the presence of plasma concentrations of 2.5 to 20% v/v. An NaDCC solution of 3,000ppm available chlorine at pH 6.6 gave satisfactory activity in the presence of 20% plasma, whereas NaOCl solutions were inactivated at chlorine concentrations up to 5,000ppm at pH 7.2, 9.0 and 10.6. In the same study it was shown that an NaDCC solution of 5,000ppm available chlorine at pH 6.6 produced a 5-6 log reduction (99.999 to 99.9999% reduction) in a suspension of 3.6×10^8 organisms per ml ***Bacillus subtilis spores***, within 5 minutes and a 5 log reduction at 200ppm within 30 minutes. An NaOCl solution at pH 10.6 produced a 3-4 log reduction in 5 minutes at 5,000ppm and had little or no activity at 200ppm after 30 minutes.

Mycobacteria

The activity of NaOCl and NaDCC at concentrations of 6,000ppm available chlorine were compared as mycobactericidal agents in ***Mycobacterium tuberculosis***-contaminated suspensions (suspension test) and stainless steel surfaces (carrier test) (7). In the absence of sputum, after a 1 minute contact the NaOCl achieved a 2 log reduction in both the suspension and carrier test, whereas the NaDCC achieved a 4 log reduction in the suspension test and 3 log reduction in the carrier test. In tests with added sputum, the NaOCl achieved a 2 log reduction for both the suspension and carrier tests, whereas the NaDCC achieved a 4 log reduction with the suspension test and 2 log reduction with the carrier test.

Viruses

A test developed to assess the surface activity of disinfectants against viral preparations dried onto coverslips included NaDCC and NaOCl formulations (8). Each coverslip, containing approximately 3 x 10^9 plaque forming units of ***Herpes simplex*** virus type 1 was dried before immersing in the disinfectants. At 2,500ppm available chlorine, the NaOCl solution showed a 2.5 log reduction after 1 minute, whereas the NaDCC solution showed a 4.9 log reduction. No virus recovered after 5 minutes with either formulation. At 1,000ppm no virus recovered after 10 minutes with either formulation but again the NaDCC formulation showed an approximate 2-fold better log reduction after 5 minutes than the NaOCl formulation.

Using a quantitative suspension test method, the antiviral activity of NaOCl and NaDCC against ***Human immunodeficiency virus (HIV)*** was investigated (9). Viral suspensions containing between 10^4 and 10^5 virus particles per ml in 0.9% saline solution were prepared, both with and without 10% v/v plasma added, to simulate clean and dirty conditions. A 4-5 log reduction was achieved in 2 minutes both at a concentration of 50ppm available chlorine under 'clean' conditions and also at a concentration of 2,500ppm available chlorine with 10% plasma for both formulations. Addition of NaDCC and NaOCl solutions at 10,000ppm available chlorine to equal volumes of contaminated blood (giving a final available chlorine concentration of 5,000ppm of blood) was sufficient to produce a total kill within 2 minutes.

All the above test results demonstrate the rapid and wide spectrum activity of NaDCC as a microbicide, and it's superior activity over NaOCl, particularly when there is organic contamination.

4.0 PUBLISHED GUIDELINE DILUTIONS

Infection control programmes should clearly define and standardise methods for decontamination (eg sterilization, disinfection and cleaning) of equipment and the environment. They should ensure that the same disinfectants and concentrations are used for similar purposes throughout.

The use of chlorine products to control infections in the medical arena has a long and successful history. One of the earliest records dates back to 1791 when chlorine gas was used to fumigate hospitals. However, it was in the middle to late 19th centuries when chlorine solutions became widely used in the medical environment and their wide use continues today throughout the world. The popularity of chlorine is deserved because of its proven potency and wide range of effectiveness as a biocide. It is easy to apply, measure and control; it is relatively free from toxic and physiological effects; it is inexpensive. Other agents may equal or even excel in any one of these characteristics, but there is none that combines them in such an advantageous way.

This long history of use has enabled authoritative guidelines on usage to be recommended by various internationally recognised organisations. Some of these published guidelines are summarised below:

4.1 Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV)

Blood or aspired fluid spillage. Flood spillage with solution and subsequently wipe over the surface.

Recommended solution strength: 5,000-10,000ppm available chlorine
(10, 11, 12, 13, 14, 15, 16, 17).

Alternatively, chlorine-containing granules are recommended to absorb and disinfect the spillage.

4.2 Laboratory Discard Jars, Pipettes etc.

Disinfection of laboratory pipettes, discard jars etc.
Recommended solution strength: 2,500ppm available chlorine (10).

4.3 General Environmental Disinfection in High Risk Areas

Disinfection of surfaces in high risk areas, eg operating theatres, post-mortem rooms, labs etc.

Recommended solution strength: 1,000-5,000ppm available chlorine
(10, 11, 12, 13, 14, 16, 17).

Surfaces are cleaned and disinfected.

4.4 Intermediate and Low Risk Areas

There are numerous and very varied recommendations for disinfection and/or cleaning in intermediate and low risk areas. NB: Although termed 'Intermediate' or 'Low Risk', it is essential that infection control procedures are clearly defined for these areas.

5.0 ASSOCIATION FRANÇAISE DE NORMALISATION (AFNOR) STANDARDS

When choosing a standard method for testing Klorsept products, the criteria considered were to select a technique that was precise, reproducible and standardised, with clearly defined microbial strains, materials, inoculum and cultures. The French AFNOR standards (which are used throughout Europe and are accepted in international markets) are a homogenous system based on standardised methods and vocabulary, that allow positive evaluation of bactericidal, fungicidal, sporicidal and virucidal activity. In every case the activity criteria is based on 5 log destruction (99.999%) of microorganisms, under standardised experimental conditions (inocula, contact time, temperature, materials, media and reagents), using suspension and carrier tests, with or without interfering substances.

In the majority of instances (for intermediate and low risk areas - refer to Section 2), disinfectants are principally required to reduce the bacterial populations and restrict their spreading over surfaces. In other circumstances (for high risk areas), disinfection is required to have a lethal action on bacteria, viruses, fungi and spores.

Being cognisant of the various published recommended guidelines for chlorine disinfection (Section 4.0) and the needs to establish in-use dosages necessary to achieve a recommended in-use microbicidal activity (Section 2.0), Medentech commissioned a series of independent evaluations by accredited laboratories to determine the in-use concentration required to conform with AFNOR standards.

The tests undertaken are summarised in Appendix I.

5.1 Intermediate and Low-Risk Areas (General Environment)

For dosage requirements in low-risk and intermediate-risk areas, evaluations were undertaken for the bacterial strains ***Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Enterococcus faecium*** and the mycobacterial strain ***Mycobacterium smegmatis*** in suspension tests without and with interfering substances (ref. Appendix I). A concentration of 100ppm available chlorine conformed to the standard (NFT 72 151) without the interfering substance and a concentration of 150ppm available chlorine conformed to the standard (NFT 72 170) with an interfering substance (milk).

Where the fungal strain ***Candida albicans*** was tested in suspension, a concentration of 50ppm available chlorine conformed to the standard (NFT 72 201).

In surface carrier tests (glass disc), a concentration of 100ppm available chlorine conformed to the standard (NFT 72 190) for the five bacterial strains indicated above.

In addition, Klorsept was tested to comply with Circular No.100 (24th November 1978) of the Ministry of Health in Italy (25) in a suspension test, both with 20% human serum as the interfering substance, and without an interfering substance at a maximum available chlorine concentration of 140ppm. The product was tested against ***Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Pseudomonas mirabilis, Klebsiella pneumoniae, Salmonella typhi, Salmonella paratyphi A., Salmonella typhimurium, Salmonella faecalis, Proteus vulgaris*** and

Candida albicans (10^{10} microorganisms per ml). In the absence of the human serum, complete inactivation occurred between 3 and 10 minutes and with the human serum between 6 and 30 minutes.

Activity at a solution strength of 200ppm available chlorine was evaluated using the AOAC Use Dilution Test against *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Aerobacter aerogenes, Bacillus subtilis and Candida albicans*. At 10 minutes, no growth was observed (29).

It is concluded that an in-use concentration of 200ppm available chlorine is sufficient for low-risk and intermediate-risk areas, giving proven mycobicidal, fungicidal and bactericidal activity.

5.2 High-Risk Areas

For dosage requirements in high-risk areas, the product must also be sporicidal. In a suspension test, a concentration of 650ppm available chlorine conforms to the standard (NFT 72 231).

Sporicidal activity was also evaluated to comply with circular No.100 (24 November 1978) of the Ministry of Health in Italy (25). Tests were carried out according to methods described by Borick et al (26) and Snyder et al (27) against spores of ***Bacillus subtilis*** (types a and b), ***Bacillus sphaericus, Bacillus arothermophylus, Bacillus globigii, Clostridium tetani, Clostridium perfringenes*** USDA, both in the presence and absence of 20% blood serum. Inactivation was less than one hour for all microbial spores in the absence of blood serum and less than two hours in the presence of blood serum. In accordance with the AOAC Official Methods of Analysis (for U.S. EPA registration) (28) spores of ***Bacillus subtilis*** and ***Clostridium sporogenes*** were impregnated on knots of silk suture threads and porcelain cylinders, maintaining a 10 hour exposure at 20°C. Ninety replicates of each test were undertaken and there were no surviving spores in any replicate.

It is concluded that an in-use concentration of 1,000ppm available chlorine is sufficient for high-risk areas, giving proven sporicidal, mycobicidal, fungicidal and bactericidal activity. This also complies with many published guideline recommendations (10, 11, 12, 14, 16, 17).

5.3 HIV and HBV

Body Fluid Spillages

The use of chlorine-containing granules has been evaluated and recommended following several studies (9, 11, 18, 19, 20). NaDCC granules have the advantages of producing higher available chlorine, containing the spillage, and needing a contact time of 2-3 minutes only (refer to Klorsept Granules Technical Report).

For flooding a gross spillage, a solution 10,000ppm available chlorine is recommended (10, 11, 12, 15, 16, 17).

Virucidal activity was assessed to comply with Circular No.100 (24 November 1978) of the Ministry of Health in Italy (25). Activity was assessed against ***Herpes simplex*** virus and ***Hepatitis B*** virus on instruments, both with and without blood serum as the interfering substance,

at a maximum concentration of 140ppm available chlorine. With ***Herpes simplex***, the virus was incubated for 30 minutes after disinfection and then observed for up to ten days. No activity was observed. With the ***Hepatitis B*** virus, the destruction rates were observed by electron microscope. Complete elimination was observed in 45 minutes without the serum and 60 minutes with the serum.

(Note that at a concentration of 10,000ppm available chlorine, the inactivation time will be less than one minute with or without serum. For an explanation of the relationship between concentration and time, refer to Appendix II).

(Note that chlorine-release agents are not recommended for urine spillages due to the reaction with uric acid releasing chlorine gas (21)).

6.0 KLORSEPT AND KLOR-KLEEN DILUTION GUIDELINES

The individual responsibility for the issue and control of guideline dilutions and recommendations for disinfection rests with appropriate medical authorities and infection control personnel.

The following guidelines are proposals based upon efficacy studies and published guidelines:

see following pages .....

AREA OF USE	METHOD OF USE	KLORSEPT/KLOR-KLEEN SOLUTION STRENGTH Available Chlorine
HIV AND HBV Body Fluid Spillage. (Not urine spillage)	Shake Klorsept Granules on spillage to completely cover and absorb fluid. Wait 2-3 minutes and scoop up the absorbed product. Wipe over the surface with Klorsept solution. Dispose of waste. If granules are not available, the area should first be covered with paper towelling or other absorbent material and then a Klorsept solution should be poured over the absorbent material and left for 10 minutes. Next, the whole spill is wiped up with fresh absorbent material and placed in a contaminated-waste container. The surface should then be disinfected with a Klorsept solution.	- 10,000ppm
Contaminated surfaces and equipment.	Wipe over surfaces with Klorsept solution. Metallic surfaces should be rinsed afterwards. Immerse items for 60 minutes.	5,000ppm
HIGH RISK AREAS Discard jars; pipettes, slides etc.	Submerge discard items for 60 minutes before disposal.	2,500ppm
Operating theatres, post-mortem rooms, burns unit, intensive care, isolation units, clinical and pathology laboratories etc.	Clean surfaces and then wipe over with Klorsept solution. Metallic surfaces should be rinsed afterwards.	1,000ppm

AREA OF USE	METHOD OF USE	KLORSEPT/KLOR-KLEEN SOLUTION STRENGTH Available Chlorine
GENERAL ENVIRONMENT INTERMEDIATE AND LOW-RISK AREAS Diagnostic rooms, sterile services, kitchens, cafeterias, hydrotherapy pool surrounds, toilets, trolleys etc. Bedpans, linen, mops, eating utensils.	Wipe over surfaces with Klorsept solution. Where detergency is required, use a Klor-Kleen solution, which enables disinfection and cleaning in a one-step operation. Immerse items, linen etc. for 15 minutes.	200ppm

Notes: Klorsept and Klor-Kleen are not recommended for items that require sterilization. They are not recommended for prolonged immersion of metallic items that are subject to corrosion.

Instructions and precautions on the packs should be carefully followed.

7.0 KLORSEPT AND KLOR-KLEEN PRESENTATIONS

Demonstration of the efficacy of Klorsept products is an essential feature. However, it is also necessary to consider the practical application and usage.

It is essential that dilutions can be easily achieved, without the need for complicated evaluations, or the weighing or measuring out of concentrated powders or liquids.

There should not be a wide range of application rates for essentially the same end uses. This only serves to complicate infection control programmes and to confuse users. The dilutions recommended in the previous section reflect this need and yet comply with published recommendations and efficacy testing.

The Klorsept and Klor-Kleen presentations have been formulated to ensure that in-use dilutions are easily understood and achieved, as follows:

Tablet	Dilution Rate		Available Chlorine p.p.m.
	No. Tablets	No. Litres	
Klorsept 17	1 1	5 1	200 1,000
Klor-Kleen	1	5	200 (with detergent)
Klorsept 87	1 1 1 2	5 2 1 1	1,000 2,500 5,000 10,000

8.0 THE KLORSEPT ADVANTAGE

* Klorsept has a demonstrable rapid and broad spectrum of activity. This activity has been independently verified (AFNOR).

* The range is conveniently available in the form of safe, rapidly soluble effervescent tablets (Klorsept 17 and 87) for easy disinfection of low, intermediate and high risk areas.

  Effervescent tablets incorporating a compatible detergent are also available (Klor-Kleen).

  For body fluid spillages, the product is also available in granular format, to ensure rapid disinfection and containment of the spillage (Klorsept Granules). Klorsept Granules contain 60% available chlorine and no effervescent base (an effervescent base not only reduces the available chlorine but also tends to promote the release of chlorine gas. Additionally, an effervescent base does not coagulate a blood spillage satisfactorily).

* The Klorsept range is easy and safe to transport and to handle (does not spill or leak) and takes up far less storage space than liquid products.

* In-use dilutions are easily understood and achieved and are in compliance with many published guidelines.

* Unlike many other disinfectants, and particularly chlorine products, Klorsept has great stability:

Klorsept 17 and 87	-	3 years
Klorsept Granules	-	2 years
Klor-Kleen	-	2 years

  (Hypochlorites typically degrade in a matter of months).

* Cost of in-use dilutions are easily evaluated and are inexpensive (14). In addition, there are further cost benefits due to reduced waste (liquids and powders are often overdosed, whereas dosing with Klorsept is exact) and reduced staff time (in measuring out liquids and powders, or evaluating dosage requirements and dilutions).

* Klorsept and Klor-Kleen have consistent quality and reliable strengths. Liquids and powders are produced to various strengths and compositions (eg bleaches, hypochlorites, are available from 1%, 2%, 5%, 5.25%, 10%, 12%; this inconsistency is difficult to incorporate in an effective infection control programme). The tablet strengths of Klorsept and Klor-Kleen have been specifically produced to meet dilution requirements in an easily understood presentation, eg 1 tablet per litre, 1 tablet per 5 litres (bucket). This enables a practical application.
* The derivatives of the active ingredient of the Klorsept range (isocyanurate) are relatively non-toxic and are biodegradable in the environment (22, 23, 24).

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APPENDIX I

AFNOR STANDARDS

Method and Reference	Membrane Filtration AFNOR NF T 72-151
Objective	Bactericidal Activity.
Strains	*Pseudomonas aeruginosa* CNCM A 22 - CIP A 22 *Escherichia coli* (ATCC 10536) CNCM 54127 - CIP 54127 *Staphylococcus aureus* (ATCC 9144) CNCM 53154 - CIP 53154 *Enterococcus faecium* (ATCC 10541) CNCM 5855 - CIP 5855 *Mycobacterium smegmatis* CNCM 7326 - CIP 7326
Inoculum	Spectrophotometer-adjusted suspension of agar culture obtained under specified conditions. Number of viable cells in presence of antiseptic or disinfectant.
	$0.5\text{-}1.5 \times 10^8$/ml
Contact Time and Temperature	5 minutes. 20°C.
Elimination of Antiseptic or Disinfectant	Transfer of microorganism-disinfectant mixture into filtration apparatus. Wash under conditions defined by preliminary test. Possible use of neutralizer in culture medium.
Subculture	Membrane placed on agar medium. Incubation at 37°C for 48 hours (7 days for *M. smegmatis).*
Interpretation	Determine the lowest concentration of disinfectant required to reduce by at least 10^5, in 5 minutes, at 20°C, the number of cells of each of the five strains. Retain as bactericidal concentration the highest of the five concentrations determined in this manner.

Method and Reference	Dilution-Neutralization AFNOR NF T 72-170
Objective	Bactericidal Activity in the presence of interfering substances.
Preliminary Conditions	The antiseptic or disinfectant must conform to test standards 72-150 or 72-151.
Strains	*Pseudomonas aeruginosa* CNCM A 22 - CIP A 22 *Escherichia coli* (ATCC 10536) CNCM 54127 - CIP 54127 *Staphylococcus aureus* (ATCC 9144) CNCM 53154 - CIP 53154 *Enterococcus faecium* (ATCC 10541) CNCM 5855 - CIP 5855 *Mycobacterium smegmatis* CNCM 7326 - CIP 7326
Inoculum	Spectrophotometer-adjusted suspension of solid medium culture obtained under specified conditions. Number of viable cells in presence of antiseptic or disinfectant.
	1-3 x 10^8/ml
Experimental Test Conditions	Contact Time and Temperature : 5 minutes. 20°C. Interfering Substances : Powdered milk.
Elimination of Antiseptic or Disinfectant	Transfer into suitable neutralizer determined during preliminary test.
Subculture	Inclusion in agar medium.
	Incubation at 37°C for 48 hours (7 days for *M. smegmatis).*
Interpretation	Determine the lowest concentration required for disinfectant to reduce by at least 10^5, in 5 minutes, at 20°C, in the presence of interfering substances, the number of cells of each of the five strains. Retain as bactericidal concentration in the presence of the interfering substance the highest of five concentrations determined in this manner.

Method and Reference	Germ Carriers AFNOR NF T 72-190
Objective	Antibacterial activity for surface decontamination.
Preliminary Conditions	The disinfectant must conform to test standards 72-150 or 72-151.
Strains	*Pseudomonas aeruginosa* CNCM A 22 - CIP A 22 *Escherichia coli* (ATCC 10536) CNCM 54127 - CIP 54127 *Staphylococcus aureus* (ATCC 9144) CNCM 53154 - CIP 53154 *Enterococcus faecium* (ATCC 10541) CNCM 5855 - CIP 5855 *Mycobacterium smegmatis* CNCM 7326 - CIP7326
Inoculum	Spectrophotometer-adjusted suspension of solid medium culture obtained under specified conditions, diluted in skimmed milk. Place on germ carrier - dry at 37°C. Number of viable bacterial cells on germ carrier $\geq 10^6$. (checked on control carriers kept at room temperature during testing).
Experimental Test Conditions	Contact Time and Temperature : 30 minutes at 20°C. Carriers : Glass slides. Interfering Substances : None.
Elimination of Antiseptic or Disinfectant	Dilution and membrane filtration, but elimination of disinfectant has not been demonstrated experimentally.
Subculture	Transfer of membrane and inclusion of germ carrier in agar. Incubation at 37°C, at least 5 days.
Interpretation	Determine the lowest concentration required for disinfectant to reduce by at least 10^5, by killing and inhibiting growth, the number of cells of each of the four strains. Retain as antibacterial concentration for surface decontamination the highest of four concentrations determined in this manner.

Method and Reference	Membrane Filtration AFNOR NF T 72-201
Objective	Fungicidal activity.
Strains	*Candida albicans* (ATCC 2091) CNCM 1180-79 - CIP 1180 79
Inoculum	Spectrophotometer-adjusted suspension of corn kernels or agar medium cultures according to strains and under conditions defined. Number of viable micromycetes cells in presence of disinfectant or antiseptic.
	$\geq 1.0 \times 10^7$
Contact Time and Temperature	15 minutes at 20°C.
Elimination of Antiseptic or Disinfectant	Transfer into filtration apparatus. Washing under conditions defined by preliminary test. Possible use of neutralizer in culture medium.
Subculture	Membrane placed on agar medium (in duplicate).
	4-day incubation at 24°C (48 hours at 30°C for *C. albicans).*
Interpretation	Determine the lowest concentration required for disinfectant to reduce by at least 10^5, in 15 minutes at 20°C, the number of fungi spores. Retain as fungicidal concentration the highest concentration determined in this manner.

Method and Reference	Membrane Filtration AFNOR NF T 72-231
Objective	Sporicidal activity.
Strains	*Bacillus subtilis* var. *niger* (ATCC 9372) CNCM 7718 - CIP 7718
Inoculum	Titrated suspensions of spores obtained from cultures prepared under defined conditions. Number of viable spores in presence of disinfectant or antiseptic: 1×10^7/ml
Contact Time and Temperature	1 hour at 20°C.
Elimination of Antiseptic or Disinfectant	Transfer into filtration apparatus. Washing under conditions defined by preliminary tests. Possible use of neutralizer in culture medium.
Subculture	Membrane placed on agar medium (in duplicate).
	48 hours incubation at 30°C (in anaerobiosis and at 36°C for *C. sporogenes).*
Interpretation	Determine the lowest concentration required for disinfectant to reduce by at least 10^5, in 1 hour at 21°C, the number of bacterial spores. Retain as sporicidal concentration the highest concentration determined in this manner.

APPENDIX II

The Effectiveness of Disinfectants and Relationship Between Concentration and Time (C.t values)

It is difficult to compare efficiency of disinfectants, given the wide variety of protocols, test methods, microbial strains and other physical and chemical conditions that will affect the effectiveness of the disinfection process.

It is for this reason that Medentech has chosen the AFNOR (Association Française de Normalisation) Standards to assess the effectiveness of it's environmental disinfectants. These standards are clearly defined and specifically designed to determine disinfectant concentrations required under standardised conditions and methods. In each case, a 99.999% destruction is required for specified microorganisms.

When comparison is required for differing test methods and different disinfectants, then difficulties arise. Selection of disinfectants requires careful interpretation of laboratory studies, operational experience and careful observation. The following points are relevant:

- Generally speaking, the higher the concentration of the disinfectant, the shorter the time is required for inactivation of microorganisms.
- The higher the temperature, there is usually a greater effectiveness of the disinfectant (and vice versa).
- The longer the exposure time, the greater is the opportunity for inactivation.
- Values for disinfectant concentration and contact time can be expressed in terms of a "C.t" ratio (1). Empirically this is expressed as:

$$k = C^n.t$$

where

k = constant for the specific microorganism exposed under specific conditions, in mgs/litre/ minute.

C = concentration of the disinfectant, in mgs/litre (ppm)
n = coefficient of dilution.
t = contact time necessary for a given percentage of inactivation, in minutes.

For practical applications, 'n' is assumed to be equal to 1.

So that, under defined conditions, for a fixed percentage of inactivation of a specific organism, a disinfectant may require a concentration of 600ppm for five minutes giving a C.t value of 3,000 (k = 600 x 5). From this, it can be evaluated that at a concentration of 6,000ppm, inactivation will be complete within 0.5 minutes (3,000 ÷ 6,000).

Use of the C.t ratio can enable quick and reliable interpretation of data.

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