

Control Plus concentrate

Specialised Cleaning and High Level Disinfecting Fluid Technical Information

Description & Application:

Control Plus is a complex blend containing the latest dodecylamine based structures, solvents and fully non-toxic, biodegradable detergent. The formulation does not contain any hazardous aldehydes or chlorine generating components.

The formulation is highly effective as a cleaner and terminal high level disinfectant (HLD) against bacteria, bacterial spores, fungi and viruses. The product is designed to eliminate the risk of cross-infection from viruses, fungi and bacteria. Control Plus does not simply render the microorganisms inert but has been demonstrated to kill these by disrupting the RNA of the microorganisms.

It is safe to use on any surface and is odourless and colo

Control Plus is available for supply as a concentrate – fragrant and non-fragrant (this data sheet), as a Ready-to-Use (RTU) solution and as an impregnated wipe. The RTU and Wipe products are described fully in separate Technical Data Sheets (TDS).

Primary features attributable to Control Plus concentrate are:

- Suitable for high level disinfection and cleaning, contains powerful germicides;
- Low toxicity, does not contain chlorine or aldehyde compounds;
- Highly effective over a wide range of viruses, bacteria, fungi, yeasts and moulds, including MRSA, Hepatitis B and HIV agents;
- Highly effective against bacterial spores;
- Effective against the difficult non-enveloped type viruses such as Polio, Adenovirus and Norovirus;
- Non-selective;
- Versatile, simple to use and cost effective;
- Approved by accredited laboratories.

Applications

Control Plus concentrate is ideal for removing biohazards in hospitals, health centres, dentists, vets, nursing homes, laboratories, food preparation areas and any environment where the risk of cross-infection needs to be eliminated, e.g. cruise ships.

Control Plus is suited for cleaning and disinfection of hard surfaces, walls, floors, glasswork and contaminated laundry.

It can also be used to disinfect medical and surgical instrumentation.

It can also be used to disinfect hairdressing equipment.

Compatibility

Control Plus concentrate is compatible with a wide range of fabrics, rubbers, plastics and hard surface materials when diluted to normal working strength.

In the concentrate form there may be slight staining or attack on some materials such as aluminium, zinc and some plastics so care needs to be exercised prior to dilution.

Health and Safety

Control Plus is not flammable and is neither a known or suspected carcinogen, is non-hypoallergenic, and is fully biodegradable.

Control Plus is classed as Corrosive to skin and eyes in the concentrate form but is non-hazardous when diluted to normal working strength and used according to the specified user directions.

Control Plus is intended for external use only.

In the 'concentrate' form contact with skin and eyes should be avoided. Suitable protective clothing, gloves and eye/face protection should be used

However when diluted to normal working strength **Control Plus** can be safely used in contact with skin and in the 'Ready-to-Use' form the product is classed as being non-harmful.

See Safety Data Sheets for details.

Typical Properties

Appearance	Pale straw coloured liquid
Odour	Slight amine (fishy) odour
pH, (typical)	12.4 units (neat)
	11.6 (10% solution)
	11.2 (5% solution)
	11.0 (1% solution)
Density, g/cm³ @ 20 °C	1.02 (neat)
Solubility in water	Complete
Flash Point (Abel closed cup)	None

Shelf Life of Concentrate

4 years in unopened original containers when stored between 5 °C and 35 °C out of direct sunlight.

Control Plus in contrast to other disinfectants is capable of penetrating the outer membranes of the bacteria and viruses and as a result renders the genome material within the cell inactive. This is in contrast to other disinfectants in the marketplace that are composed of chemicals that may well inactivate the cells for a period of time, preventing growth, but after a period the cells will regenerate and multiply. **Control Plus** will inactivate the cell to the point where the RNA is destroyed and therefore preventing replication.

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Control Plus will also attack all single strand transcriptase positive and transcriptase negative viruses within similar families.

Control Plus has been thoroughly tested by independent laboratories and demonstrated to be effective against gram negative and gram positive bacteria, viruses and fungi/yeasts.

Efficacy data has been raised against the following specific organisms: Bacteria:

Acinetobacter calcoaceticus

Acinetobacter baumannii

Bacillus stearothermophilus

Bacillus cereus

Campylobacter jejuni

Clostridium difficile

Clostridium perfringens

Enterobacter sakazakii

Enterococcus hirae

Enterococcus faecalis Vancomycin Resistant (VRE)

Escherichia coli

Escherichia coli ESBL (Extended Spectrum beta-Lactamases)

Escherichia coli - O157 Strain

Klebsiella pneumonia

Legionella pneumophila (Sero Group 1)

Listeria monocytogenes

Methicillin resistant Staphylococcus aureus (MRSA)

Pseudomonas aeruginosa

Salmonella typhimurium

Serratia marsescens

Shigella sonnei

Stenotrophomonas maltophilia

Staphylococcus aureus

Vibrio parahaemolyticus

Yersinia enterocolitica

Mycobacterium terrae (Note – has been used for testing against TB)

Mycobacterium tuberculosis

Mycobacterium avium

Viruses: -

Avian flu (Bird Flu – Strain H5N1)

Hepatitis B and C

HIV-1 virus

Influenza virus (Strain H3N2)

Murine norovirus

Parainfluenza 3 virus,

Polio virus

Vaccinia virus.

Feline Calicivirus (Human norovirus surrogate)

Feline Coronavirus (human surrogate for SARS)

Adenovirus

Spores:-

Bacillus cereus

Bacillus subtilis

Clostridium difficile

Clostridium perfringens

Fungi and Yeasts: -

Aspergillus niger

Trichophyton equinum

Trichophyton mentographytes

Aspergillus fumigatus

Candida albicans

Microsporum canis

Microsporum gypseum

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Directions for Use

Control Plus concentrate product requires dilution prior to use. Application:

Medical Devices

For Manual Disinfection of instruments and equipment:

Stage 1:

Put on PPE and wash medical device carefully in an Enzymatic cleaner and rinse.

Make Control Plus solution at 1:20 (5%) or 50ml per litre Stage 2:

Instruments and devices that are non-autoclavable, particularly those that are heat-sensitive or delicate in nature (flexible and rigid endoscopes, etc.), require disinfection with specially designed chemical alternatives like Control Plus Concentrate instrument disinfectant

Control Plus concentrate (High Level Instrument Disinfectant) is recommended for use, as follows: -

- Make sure that instrument has been thoroughly cleaned (see STAGE ONE above)
- Soak for 5 10 minutes making sure that all internal channels are flushed through. This ensures bactericidal, fungicidal, virucidal, mycobactericidal and sporicidal performance is attained. Note: Ensure that all spaces and recesses are completely filled with Control Plus fluid and no air pockets exist
- Rinse in sterile water and dry with sterile material
- The medical device is now ready for use

A policy by the practice / department to carefully monitor the above will help to reduce any potential problems. Sychem would recommend to conduct the MEC test at least once per day.

Changing from an Aldehyde based disinfectant (Glutaraldehyde and OPA) to Control Plus

The aldehyde will be absorbed into the walls of all plastics including flexible endoscopes and if no pretreatment is carried out there will be a chemical reaction which can cause discolouration. To prevent this Sychem would recommend to soak all plastic instruments, syringing tubes, connection

tubes, flexible endoscopes etc in a solution of diluted enzymatic cleaner. Then rinse thoroughly.

Non-immersible Medical Devices and Equipment

- Dilute Control Plus at 1:20 (50ml/litre, 5%)
- Apply the Control Plus solution onto a low lint cloth and wipe the relevant medical device or
 equipment ensuring the full surface of the device remains wet for at least 1 minute (ILD) or 5
 minutes (HLD).
- Rinse the surface of the medical device with a damp cloth of water.

For non-critical medical devices:

- Inspect device / instrument.
- Wipe thoroughly with Control Plus Wipes (see separate TDS) and repeat using fresh wipe(s).
- Allow to air dry
- Place in suitable holder until required for use

For maximum effectiveness, the **Control Plus** solution should be replaced every 14 days or when the measured strength falls below the recommended 5% level or if any signs of gross soiling of the solution is present.

General Surface Cleaning and Healthcare Environment:

For Intermediate Level Disinfection: Dilute Control Plus to 0.5% with water (5ml per litre) at 20°C with a 15 minutes contact time.

For High Level Disinfection: Dilute Control Plus to 5% with water (50ml per litre) at 20°C

Dispense / Spray (DO NOT MIST) **Control Plus** diluted solution directly onto the surface to be treated and wipe gently over the whole area with a clean low lint cloth.

Allow a minimum contact time of 1 minute before wiping clean or brushing to remove grease, blood and organic debris. Removal of stubborn deposits may be assisted by the use of a stiff bristle brush. Rinse treated surface with clean water if required.

Food Sector

Food Preparation Surfaces

For Intermediate Level Disinfection: Dilute Control Plus to 0.5% with water (5ml per litre) at 20°C with a 15 minutes contact time.

For High Level Disinfection: Dilute Control Plus to 5% with water (50ml per litre) at 20°C

Dispense / Spray (DO NOT MIST) **Control Plus** diluted solution directly onto the surface to be treated and wipe gently over the whole area with a clean low lint cloth.

Allow a minimum contact time of 1 minute before wiping clean or brushing to remove grease, blood and organic debris. Removal of stubborn deposits may be assisted by the use of a stiff bristle brush. Rinse treated surface with clean water if required.

Note: Food preparation surfaces should be allowed to dry before use.

COP (Clean Out of Place)

Instruments and devices that require disinfection with specially designed chemical alternatives like Control Plus is recommended for use, as follows:

For Intermediate Level Disinfection: Dilute Control Plus to 0.5% with water (5ml per litre) at 20°C with a 15 minutes contact time.

For High Level Disinfection: Dilute Control Plus to 5% with water (50ml per litre) at 20°C

- Make sure that instrument has been thoroughly cleaned
- Soak for 5 10 minutes in the diluted Control Plus solution, making sure that all internal channels are flushed through. This ensures bactericidal, fungicidal, virucidal, mycobactericidal and sporicidal performance is achieved
 - **Note**: Ensure that all spaces and recesses are completely filled with Control Plus fluid and no air pockets exist
- Rinse in sterile, Deionised (DI) or Reverse Osmosis (RO) water and dry

CIP (Clean In Place)

For Intermediate Level Disinfection: Dilute Control Plus to 0.5% with water (5ml per litre) at 20°C with a 15 minutes contact time.

- Flush for 30 minutes making sure that all internal channels are flushed through.
- Ensure that all spaces and recesses are completely filled with Control Plus fluid and no air pockets exist
- Rinse is optional
- Allow to dry

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CONTACT DETAILS:

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For any further information, please contact your distributor or Sychem.

Approval and Test Data for Control Plus

1. Approvals.

- 1.1 **Control Plus** has been satisfactorily tested by leading laboratories for viral, bacterial and fungi testing. Micropathology Ltd, Coventry;
 - H.I.R.L (Hospital Infection Research Laboratory) City Hospital Birmingham
 - Bodycote Materials Testing, Law Laboratories, Birmingham.
 - Texcell Laboratory (Part of Institute Pasteur®), Paris, France
 - Health Protection Agency, UK.
 - Retroscreen Virology Ltd (Queen Mary Hospital, University of London)
- 1.2 **Control Plus** has been satisfactorily tested as a disinfectant and approval granted by the UK Department for Environment, Food and Rural Affairs (DEFRA) for the following:
 - General Orders, as defined in the Diseases of Animals (Approved Disinfectant) Order 1978 at a dilution of 1 part disinfectant to 19 parts of water.
 - The Disease of Poultry Order and The Avian Influenza and Influenza of Avian Origin in Mammals Order at a dilution rate of 1 part disinfectant to 9 parts of water.
- 1.3 **Control Plus** has been satisfactorily tested as an Intermediate Level disinfectant against Tuberculosis at a dilution of 0.25% following a contact time of 15 minutes.

2. Test compliance

- 2.1 Testing carried out according to;
 - BS6471,
 - BS6424.
 - BS6905.
 - EN1275
 - EN1276
 - EN13704
 - EN 13727
 - EN 13727 - EN14347
 - LINIAUA1
 - EN 14348EN13697
 - EN13704
 - LIVIS/04
 - EN14476
 - EN 14561
 - EN 14562
 - EN 14563
 - EN16615 and
 - AFNOR (EC) procedures.
- 2.2 **Control Plus** has been tested for bactericidal efficacy according to BS EN 1276 (European Suspension Test) and demonstrates a > log 5 reduction in counts at 20 °C for all three time intervals selected.
- 2.3 Basic fungicidal and yeastical activity tested in accordance with BS EN 1275 (European Suspension Test) and demonstrates a > log 5 reduction in counts at 20 °C after 1, 2 and 5 minute contact times.
- 2.4 Sporicidal Efficacy tested in accordance with BS EN 14347 and achieved >5 log 10 reduction in all test organisms for all contact times down to 1 minute.
- 2.5 Sporicidal Efficacy tested in accordance with BS EN 13704 and achieves a >3 log 10 reduction in all test organisms for all contact times down to 1 minute.
- 2.6 Virucidal activity tested according to norm NFT 72-180 and passes requirement (> 4 log 10 reduction at 1 minute exposure).
- 2.7 Bactericidal Efficacy for disinfection of medical instruments tested in accordance with BS EN 13727 and achieved >5 log 10 reduction in all test organisms.
- 2.8 Bactericidal and Fungicidal Efficacy in food, industrial and institutional areas tested in accordance with BS EN 13697 and achieved >5 log 10 reduction within a 5 minute contact time.
- 2.9 Complies with BS ISO 4120:2004, food taint test.
- 2.10 Feline calicivirus (Human norovirus surrogate), polio virus and adenovirus tests carried out in accordance with test standards EN 14476.
- 2.11 Bactericidal efficacy against Mycobacterium tuberculosis established using BS EN 14348.
- 2.12 Bactericidal efficacy against Mycobacterium tuberculosis following a contact time of 15 minutes and at a dilution concentration of 0.25% established.

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