



Virusolve[®]+ EDS

Concentrated High Level Disinfecting Fluid for Endoscopes & Medical Instruments Technical Information

Description & Application:

Virusolve+ EDS is a new, superior high level disinfectant (HLD) that is designed for decontamination of medical, surgical, dental and endoscopic instruments.

Virusolve+ EDS is a concentrated blend containing the latest dodecylamine based structures, fully non-toxic, biodegradable detergents and anti-corrosion agents. The formulation does not contain any hazardous aldehydes or chlorine generating components.

This formulation is a highly effective and safe process for the cleaning and disinfection of endoscopes, medical, dental and delicate instruments against a wide range of viruses, bacteria, fungi, yeasts and spores, including MRSA, Hepatitis B and HIV agents.

Virusolve+ EDS 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 offers particular benefits where autoclave decontamination cannot be used, e.g. optic probes.

Primary features attributable to Virusolve+ EDS are:

- High Level Disinfectant, suitable for disinfection and cleaning, contains powerful germicides;
- Enhanced safety:
 - Low toxicity, does not contain chlorine;
 - No glutaraldehyde or other aldehyde compounds;
 - Odourless;
- Highly effective over a wide range of viruses, bacteria, fungi and bacterial spores;
- Effective against the difficult non-enveloped type viruses such as Polio, Adenovirus and Norovirus;
- Reduced instrument damage and repair:
 - Excellent material compatibility;
 - Non-fixative;
 - Non-corrosive, will not damage delicate coatings;
 - More gentle on flexible endoscopes than Peracetic acid.
- Increased speed and efficiency:



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- Rapid reaction time – 5 minute immersion at 20 °C;
- Improved instrument availability through faster turn around times for decontamination;
- No activation required;
- cost effective – improved staff productivity, more flexible, more devices processed per litre;
- Approved by accredited laboratories.

Applications

Virusolve+ EDS is ideal for removing biohazards from medical instruments, endoscopes and other equipment used in hospitals, health centres, dentists and laboratories.

Compatibility

Virusolve+ EDS is compatible with a wide range of fabrics, rubbers, plastics and hard surface materials and will not attack metal surfaces if used in accordance with standard infection control practises at the recommended dilution rate and contact time.

Health and Safety

Virusolve+ EDS is not flammable and is neither a known or suspected carcinogen, is hypoallergenic and is fully biodegradable.

Virusolve+ EDS is certified as being non-hazardous when used according to the specified user directions.

Virusolve+ EDS is intended for external use only.

In the 'concentrate' form the product is classed as being corrosive and contact with skin and eyes should be avoided, however once diluted to working strength the solution is classed as mildly irritant.

See Material Safety Data Sheets for details.

Typical Properties

Appearance	Blue coloured liquid
Odour	Slight amine (fishy) odour
pH,	12.6 units (neat) 11.7 (10% solution) 11.2 (1% solution)
Density, g/cm ³ @ 20 °C	1.05 (neat)
Solubility in water	Complete
Flash Point (Abel closed cup)	None

Shelf Life: Concentrate – 3 years in unopened original containers when stored between 5 °C and 40 °C out of direct sunlight.

Virusolve+ EDS, in contrast to other disinfectants, is unique as it 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.

Virusolve+ EDS will inactivate the cell to the point where the RNA is destroyed and therefore preventing replication.

Virusolve+ EDS will also attack all single strand transcriptase positive and transcriptase negative viruses within similar families.

Virusolve+ EDS has been thoroughly tested by independent laboratories and demonstrated to be effective against gram negative and gram positive bacteria, viruses, spores and fungi/yeasts.

Efficacy data has been raised against the following specific organisms:

Bacteria:

Enterococcus hirae
Escherichia coli
Methicillin resistant Staphylococcus aureus (MRSA)
Pseudomonas aeruginosa
Staphylococcus aureus

Mycobacterium tuberculosis
Mycobacterium terrae
Mycobacterium avium

Viruses: -

Poliovirus-1
Feline Calicivirus (Human norovirus surrogate)
Adenovirus-5
Bovine parvovirus
HIV
Hepatitis B
Hepatitis C

Spores:-

Clostridium difficile
Bacillus subtilis

Fungi and Yeasts: -

Aspergillus fumigatus
Aspergillus niger
Candida albicans

Directions for Use

Virusolve+ EDS is supplied as a concentrated product that requires dilution prior to use and also as a Ready-to-Use (RTU) solution that requires no dilution prior to use.

Concentrate dilution:

For cleaning and disinfection applications, dilute 1 part Virusolve+ EDS concentrate in 40 parts water (i.e. a 2.5% solution or 25ml/Litre)

Note Greater strengths of up to 5% Virusolve+ EDS (i.e. 1 part in 20 parts water or 50ml/Litre) may be used where high levels of contaminants or where difficult or hazardous contaminants may be present.

Application:

For Disinfection of instruments, flexible endoscopes, medical devices and other medical equipment:

Select as appropriate from the following:

Where probes are applied to nasal or ear cavity or via endoscopes into stomach, duodenum, colon rectum or to broken/infected areas of skin and mouth:

- Wear Personal Protective Equipment (PPE) i.e. gloves and apron
- Wash probe carefully in an Enzymatic cleaner and rinse. Dry with paper towel.

Note: The enzymatic cleaner recommended by Amity is as follows:

For automated processes use either Viruzyme+, Viruzyme N or for the most arduous cleaning use Viruzyme Duo system

For manual cleaning use Viruzyme III

- Make up Virusolve+ EDS solution at 1:40 (2.5% solution)
- Immerse for 5 minutes for bactericidal, fungicidal, virucidal, tuberculocidal, sporicidal and immuno-compromised protection.

- Rinse in sterile water and dry with sterile material
- The probe is now ready for use
- Replace in double sealed pack for storage.
- Use test kit / MEC Strip to validate the decontamination process.

Under low risk conditions on intact skin where no infection is suspected:

- Inspect probe head, sleeving and connectors.
- Wipe scan-head thoroughly with Virusolve+ Wipes twice
- Allow air dry
- Store in suitable holder until required for use

For probes/transducer to be used in endocavity invasive procedures where no covers are in place or where the cover appears damaged:

- Dispose of damaged cover in yellow bin
- Wear gloves and apron and wash probe carefully in an Enzymatic cleaner and rinse. Dry with paper towel

Note: The enzymatic cleaner recommended by Amity is as follows:

For automated processes use either Viruzyme+, Viruzyme N or for the most arduous cleaning use Viruzyme Duo system

For manual cleaning use Viruzyme III

- Make up Virusolve+ EDS solution at 1:40 (2.5% solution)
- Immerse for 5 minutes for bactericidal, fungicidal, virucidal, tuberculocidal, sporicidal and immuno-compromised protection.
- Rinse in sterile water and dry with sterile material
- The probe is now ready for use
- Replace in clean holder.
- Use test kit / MEC Strip to validate the decontamination process.

This process should also be used where external procedure are being used for patients in high risk groups – HIV/AIDS/MRSA/ Biopsies and drainage procedures

For external ultrasound procedure under normal risk conditions:

- Select appropriate probe and scan patient
- Wipe scan-head thoroughly with Virusolve+ Wipes twice
- Allow to air dry
- Store in suitable holder until required for use

CHEMICAL REPROCESSING OF INSTRUMENTS STAGE TWO – HIGH LEVEL DISINFECTION

Instruments and devices that are non-autoclavable, particularly those, which are heat-sensitive or delicate in nature (flexible and rigid endoscopes, etc.), require disinfection with specially designed chemical alternatives like Virusolve+ EDS Instrument Disinfectant.

When choosing a chemical disinfectant for instrument reprocessing, several elements need to be considered:

1. The product must have secure microbiological credentials (Sporicidal, Mycobactericidal, Virucidal, Fungicidal and Bactericidal), supported by laboratory test reports.
2. The product must be safe to use (non-toxic, non-fuming, non-sensitising) ideally with minimum precautionary measures. Avoid aldehyde or glutaraldehyde based products completely.
3. The product must be compatible with all equipment and instruments with which they come into contact.
4. The product should be easy to dilute/mix, leaving little room for error.
5. Long term diluted shelf lives (14 days) with efficacy test verification methods ensure a more economic solution than the many 'one-day, throw away' alternatives.

Virusolve+ EDS (High Level Instrument Disinfectant) is recommended for use, as follows: -

- i) Make up solution at a dilution of 1:40 (2.5% in water) – 25ml Virusolve+ EDS to 1 litre water
- ii) Make sure that instrument has been thoroughly cleaned (STAGE ONE)
- iii) Immerse instrument in solution for 5 - 10 minutes making sure that all internal channels are flushed through.
- iv) Remove and rinse with purified or deionised water,
- v) Leave to dry and store in sterile packaging for re-use.

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

Changing from an Aldehyde based disinfectant (Glutaraldehyde and OPA) to Virusolve+ The aldehyde will be absorbed into the walls of all plastics including flexible endoscopes and if no pre-treatment is carried out there will be a chemical reaction which can cause discolouration. To prevent this Amity would recommend to soak all plastic instruments, syringing tubes, connection tubes, flexible endoscopes etc in a solution of Viruzyme III diluted to 1% (10ml/litre) for a minimum time of 3-4 hours but this could be extended to an overnight soak. Then rinse thoroughly.

This should eliminate 99% of the possible reaction occurring.

Disposal of spent solutions:

Flush to drain with copious water or soak up onto inert material and dispose of with clinical waste

Product is biodegradable under OECD conditions.

Analysis

When required by users, Virusolve+ EDS solutions may be checked for concentration using the procedure set out in Product Information Bulletin Sheet (PIBS) 08-004.

A simple spot test using MEC Test Strips may also be used, reference PIBS 08.

For maximum effectiveness, the Virusolve+ EDS solution should be replaced when the measured strength falls below the recommended 2.5% level or if any sign of gross soiling of the solution is present.

CONTACT DETAILS:

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For any further information, please contact your distributor or Amity.
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Packaging Details:

Virusolve+ EDS is available in the following packaging.
Users will need to specify requirements on their order.

As a Concentrate in:

- 125 ml bottle (minimum order quantity applies)
- 250 ml bottle (minimum order quantity applies)
- 1 Litre self dosing containers
- 5 Litre containers
- 25 litre container
- 10 Litre, 210 Litre and/or 1000 Litre IBC container (available upon application)

As a RTU (Ready to Use) Solution in:

- 5 Litre containers

Approval and Test Data for Virusolve+ EDS

1. Approvals.

- 1.1 Virusolve+ EDS has been satisfactorily tested by leading laboratories for virucidal, bactericidal, sporicidal and fungicidal testing.
- BluScientific (Glasgow Caledonian University)
 - H.I.R.L (Hospital Infection Research Laboratory) City Hospital Birmingham
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2. Test compliance

- 2.1 Testing carried out according to EN 1276, EN 1650, EN 13624, EN 13704, EN 13727, EN 14347, EN 14348, EN 14476, EN 14561, EN 14562, EN 14563
- 2.2 Virusolve+ EDS 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 BS EN 14476 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 Feline calicivirus (Human norovirus surrogate), polio virus and adenovirus tests carried out in accordance with test standards EN 14476.