

# TECHNICAL BULLETIN



19 Motivation Dve Wangara, WA, 6065 AUSTRALIA  
T +61 8 9302 4000 | FREE 1800 999 196 | F +61 8 9302 5000

## **AIDAL PLUS™ STERILANT**

Patented in Australia and Internationally

**AIDAL PLUS** is suitable for use in Hospitals, Dental and Medical Surgeries and Veterinary Hospitals, for the Sterilisation and High Level Disinfection of Critical and Semi Critical Medical Devices.

**AIDAL PLUS** is a polyglycol dialdehyde complex instrument disinfectant intended for general use in a surgical practice where Sterilisation or High Level Disinfection is required. It is a stable, odour suppressed, mildly acidic glutaraldehyde Sterilant and Instrument Disinfectant (High Level), which exhibits potent biocidal action against those important resistant pathogens which now challenge the performance of present and past generation glutaraldehyde disinfectants.

**AIDAL PLUS** shows several major improvements over alkaline activated Glutaraldehyde. Improved biocidal performance is achieved with reduced glutaraldehyde odour and reduced propensity for irritation and yellowing to human skin compared with alkaline glutaraldehyde preparations.

**AIDAL PLUS** has been tested in a wide array of tests and various conditions, including testing at the end of the shelf life, at the end of the re-use period, diluted to the Minimum Recommended Concentration of active material (1.5% Glutaraldehyde), and then soiled and tested in hard water against hardest to kill organisms.

**AIDAL PLUS** will not damage endoscopes or other complex medical equipment when used in accordance with directions and the instrument manufacturers instructions.

**AIDAL PLUS** has an MRC (Minimum Recommended Concentration) of 1.5% w/w glutaraldehyde. All tests for sterilant or disinfectant efficacy were conducted at the MRC or lower in accordance with strict performance standards.

### **EFFICACY DATA AND SOAK TIMES**

**AIDAL PLUS** has demonstrated performance as a bactericidal, fungicidal, virucidal, mycobactericidal and sporicidal high level disinfectant with complete efficacy under these conditions for European standards as a class IIa Medical Device (in Australia it is classified as a Class IIB Medical Device).

Due to the many varied test conditions and regulatory requirements in different countries please consult the Front Label of Aidal Plus for the relevant soak time and temperature in the country of use.

*(Continued)*

### **DISINFECTION PROCEDURES**

Thorough precleaning with an acceptable product is an essential element of any effective cleaning and disinfecting protocol. An appropriate procedure will involve at least 5 steps – preclean, rinse, disinfect, sterile rinse and dry, then store. For further technical advice please contact your local Whiteley Industries representative.

It is of critical importance that only recommended detergents be used in conjunction with

## **AIDAL PLUS.**

International authorities recommend that only a neutral detergent, a neutral enzyme cleaner or a Biofilm Remover be used as part of thorough mechanical cleaning.

**MATRIX has been shown in internationally peer reviewed published clinical data to provide excellent soil and biofilm removal from materials used in endoscopes and other medical devices (glass based testing methods have limited or no relevance).**

**SONIDET** is a neutral medical grade detergent which is also suitable for cleaning of medical devices. **MEDIZYME** is a neutral enzyme cleaner which is also suitable for cleaning medical devices.

Separate technical literature is available on each product and should be studied prior to use.

It is also of critical importance that all instruments be thoroughly rinsed prior to immersion in **AIDAL PLUS**. Care should be taken to ensure that instruments are as dry as possible prior to immersion. **AIDAL PLUS** should be carefully drained from the instruments following an appropriate immersion time. The final rinse should be with sterile water using at least 5 times the volume required to cover the instrument.

This rinsing procedure is best done as 5 rinsing procedure using enough water to immerse the instrument each time.

### **PRECAUTION WITH METAL, PLASTIC & RUBBER INSTRUMENTS**

**AIDAL PLUS** solutions should not be used with carbon steel instruments since they may produce a mild corrosion (as does distilled water) after a few hours. 24 hour continuous exposure to solutions will not affect most plastics, brass, aluminium, chrome, nickel or stainless steel. Chrome and nickel plated instruments will not be tarnished after 24 hours, with the exception of nickel plating over a beryllium base. Poorly plated, worn or corroded instruments with cracks could obviously be tarnished after processing.

**AIDAL PLUS** is not suitable for use with products made of natural rubber or plasticised PVC.

**AIDAL PLUS** contains a corrosion inhibitor, however, it is recommended that disinfected instruments do not remain in the **AIDAL PLUS** solution over extended periods of time.

The immersion time for optical instruments should not exceed the soaking time that the equipment manufacturer recommends.

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Regarding the general matter of instruments tarnishing, the manufacturer does not warrant anything beyond the above statements since it is well known that the quality of the metals, alloys, plastic parts or components can greatly vary among instrument brands. When in doubt, the customer should contact the instrument manufacturer.

### **SOLUTION LIFE**

**MANUAL SOAKING or USE IN AUTOMATED ENDOSCOPIC REPROCESSORS IS RECOMMENDED.**

**AIDAL PLUS** is chemically stable for 1 year, when stored in the original container.

**AIDAL PLUS IS INTENDED FOR RE-USE UP TO 28 DAYS OR UNTIL INDICATED BY**

**TEST STRIPS, OR UNTIL THE SOLUTION IS VISIBLY SOILED OR BECOMES CLOUDY OR DISCOLOURED.**

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**AIDAL PLUS** may be reused for up to 28 days for high level disinfection procedures. In re-use situation **COLD STERIOLOG INDICATOR STRIPS** should be used to test the solution.

### **COLD STERIOLOG INDICATOR STRIPS**

Whiteley Industries recommend the use of **COLD STERIOLOG** indicator strips to monitor the concentration of glutaraldehyde. During re-use it is logical that rinse water introduced into **AIDAL PLUS** will cause the concentration of glutaraldehyde to fall, therefore it is advisable to test the concentration each day. If the concentration of **AIDAL PLUS** falls below the MEC of 1.5% the **COLD STERIOLOG** strips will give a negative reading.

**COLD STERIOLOG** strips are available from your **AIDAL PLUS** supplier.

### **STORAGE AND DISPOSAL**

This product must be kept in locked storage to make it inaccessible for children or persons unfamiliar with its proper use. **AIDAL PLUS** should be stored at or below 25°C. **AIDAL PLUS** contains only biodegradable materials. Glutaraldehyde has been shown to be without effect at concentrations below 10 ppm. Where possible, disposal should be with copious quantities of water. Where septic systems are involved the active glutaraldehyde may be neutralised with dilute solutions of sodium bisulphite before disposal. Tests reveal that glutaraldehyde is approximately 90% biodegradable within a standard five day biodegradable test at levels below microbiological effectiveness. The container may be disposed of by thoroughly rinsing with water and then discarding through the normal waste system. It is recommended that the container be punctured prior to disposal to prevent re-use.

The bottle, lid and label are all made from fully recyclable materials where recycling is available.

Where required, residual glutaraldehyde can be neutralised by adding neutralizer. Special instructions apply. Contact your Whiteley Industries representative or distributor for further information on **GN Liquid.**]

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### **ACTIVE CONSTITUENT**

2.5% (21 g/L) w/w glutaraldehyde in the form of buffered neutral 1,5 pentanedial poly glycol complex.

### **WARNING**

**May cause sensitisation by skin contact or inhalation.**

**AIDAL PLUS** is hazardous according to the criteria of Worksafe Australia.

Glutaraldehyde can act as an irritant and sensitiser to the skin and irritates the airways of the respiratory tract. Appropriate ventilation, work practices and personal protective equipment are necessary to prevent skin contact and inhalation.

**Occupational asthma and/or rhinitis have been indicated in a number of workers exposed to glutaraldehyde AND OTHER ALDEHYDE SOLUTIONS.**

*Carcinogenicity:* Glutaraldehyde is not a carcinogen.

*Reproductive Toxicity / Teratogenicity:* There is no difference of incidence of miscarriage between those exposed to glutaraldehyde and those not exposed to the chemical.

*Mutagenicity:* The results of more recent assays have generally shown that glutaraldehyde is mutagenic *in vitro*. All *in vivo* tests to date have been negative.

Consequently, glutaraldehyde does not meet the criteria for classification as a mutagen.

## **SAFE WORKING RECOMMENDATIONS**

Glutaraldehyde is known to cause allergic reactions and skin sensitisation through skin contact or inhalation. Occupational asthma and/or rhinitis have been indicated in a number of workers exposed to glutaraldehyde.

Use only in covered airtight containers to avoid evaporation and contamination.

Avoid contact with eyes, skin and food.

Gloves should be worn at all times (Double Gloving or Nitrile gloves are internationally recommended).

Protective clothing eg. Long sleeved shirts and plastic aprons and covered impervious shoes should be worn when using glutaraldehyde.

Avoid breathing vapour. The area in which the product is used should be well ventilated at all times. Glutaraldehyde is a respiratory irritant which has a recommended TLV of 0.05 mg/L in air.

The Material Safety Data Sheet on **AIDAL PLUS** provides additional safety data, and should be read before using **AIDAL PLUS**. Consult the Material Safety Data Sheet for first aid information.

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## **GENERAL WARNING**

There is no way of predicting an individuals' response to cleaning or disinfecting products. All cleaning and/or disinfecting products have a potential to cause skin or other irritation or allergic/immune response in susceptible individuals. Direct physical contact with the skin should be avoided. If irritation does occur when using this product or any other Whiteley Medical product or cleaning solution, then the individual should be removed from direct contact with the solution until a satisfactory safe working environment for that individual is determined and made available.

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