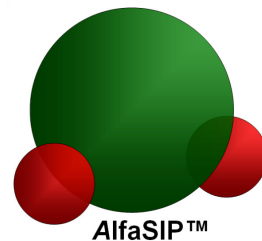


AlfaSIP™-50D RAPID DISINFECTION KIT

For use with CONTINUOUS FLOW ULTRACENTRIFUGES and other PROCESSING and LABORATORY EQUIPMENT



Disinfection and Sanitization in Place at Ambient Temperature

Compatible with Metals, Plastics and Elastomers
at recommended application concentrations and contact times

The **AlfaSIP-50D** kit produces a >99% pure solution of chlorine dioxide in water. The patented, membrane-based micro-reactor envelope technology ensures that only pure chlorine dioxide gas is diffused into the water and equipment. The production system ensures that no free chlorine can be created.

- This product is registered with the United States Environmental Protection Agency (Reg. No. 74986-5-84777), in accordance with FIFRA sec. 3(c)(7)(A), as a disinfectant and sanitizer when used as directed. As such, the product has met the antimicrobial requirements for disinfecting and sanitizing specified in the US EPA Office of Pesticide Program's Disinfection Technical Science Section (DIS/TSS) efficacy documents.
- Although the term "sanitizing" has specific antimicrobial performance conditions in the USA, as required and specified in the DIS/TSS documents, in the ultracentrifuge market, the term refers to the entire protocol of coarse cleaning, fine cleaning, disinfection, rinse-out, verification, and return-to-service — a protocol for removing bacteria and surface-clinging organic matter and slimes. A "sanitizing application" for hard, non-porous non-food contact surfaces would require specifically a 20 ppm concentration and a contact time of 5 minutes. A sanitizing protocol for ultracentrifuge rotor systems, on the other hand, could entail both a disinfection step (at 100 ppm and 10 minutes contact time) and an antimicrobial "sanitizing" step as part of the overall protocol.

- **At 100 ppm ClO₂, AlfaSIP is a highly effective disinfectant, sanitizer, and virucide.**
- **Total protection** - Disinfection / Sanitization In-Place in a closed system.
- **Time saving** - Short disinfection / sanitization time (5-10 minutes) with no heating or cooling cycle.
- **Easier to use than most other chemical disinfecting solutions** – When used according to the instructions, following the stated precautionary measures and application specifics, the product is not considered to be a contact sensitizer. Application amounts and quantities are smaller than those appropriate for many other disinfecting agents.
- **Broad range ability** - Compatible with stainless steel, most plastics & elastomers.
- **Simple procedure** for centrifuges, chromatography and ultrafiltration systems and general laboratory surfaces.

Simple, Easy-to-Use Method

AlfaSIP-50D is supplied in packs of 10 kits. One kit produces an active solution of chlorine dioxide gas dissolved in enough water to carry out 8 to 10 disinfection cycles on an Alfa Wassermann continuous flow ultracentrifuge. Once produced as directed, the solution remains at active strength for 15 days, ready for immediate use on-demand.

A package containing a membrane envelope is opened and the envelope is immersed in 50 liters of water. The solution is at full strength after ten hours. The concentration can be checked with easy-to-use, "dip-and-check" test strips.

Disinfection requires 10 minutes at 100 ppm or 20 minutes at 50 ppm. Afterwards, rinse-out is achieved rapidly with a small volume of water, and the absence of residual chlorine dioxide confirmed by use of test strips.

Highly Effective Disinfection Activity

How does AlfaSIP™ work?

AlfaSIP gas inactivates microorganisms by oxidizing key components in proteins that regulate cell metabolism. Cell death is caused by a loss of permeability control and ultimately membrane potential. By oxidizing these specific protein components, chlorine dioxide is reduced to inactive byproducts.

The chemical reaction pathway prevents the formation of free chlorine, trihalomethanes (THMs) or haloacetic acids (HAA5).

When used as directed, this chlorine dioxide-generating product is proven effective as: a **disinfectant** against: *Candida albicans*, *Listeria monocytogenes*, methicillin-resistant *S. aureus* (MRSA), *Mycobacterium bovis* (TB), *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*, *Trichophyton mentagrophytes* (athlete's foot) and vancomycin-resistant *Enterococcus faecalis*; a **virucide** against *Adenovirus type 5*, *Canine Parvovirus*, *Coronavirus*, *Feline Calicivirus*, *Hepatitis A*, *Herpes Simplex-2*, *Human Immunodeficiency Virus Type 1* (HIV-1), *Influenza-A*, *Norovirus (feline calici used as testing surrogate)*, *Poliovirus-1*, *Rhinovirus type 37*, *Rotavirus*, and *Vaccinia* and a **sanitizer** against *E. coli* (and *E. coli O157:H7*), *Klebsiella pneumonia*, *Listeria monocytogenes*, *Salmonella typhimurium* (MDRS), and *S. aureus*.

What is chlorine dioxide?

"In contrast to the use of chlorine or hypochlorous acid or bleach, chlorine dioxide is not a chlorinating agent. It does not form chlorinated organic by-products. This is an important distinction between the use of chlorine (Cl₂, HOCl, OCl⁻), and chlorine dioxide (ClO₂). In reactions with organic materials, chlorine invariably forms volatile chlorine-containing organic by-products."

"Observations and Comments on the Use of Chlorine Dioxide for the Decontamination of the Hart Office Building", Gilbert Gordon, Ph.D., Department of Chemistry and Biochemistry, Miami University, Oxford, Ohio, USA.

Chlorine dioxide is certainly not chlorine, hypochlorous acid, or bleach. In water, all of these compounds, including chlorine gas, rely on hypochlorous acid for biocidal effects.

Hypochlorous acid ionizes in water producing the OCl⁻ radical that is approximately 1% as effective as the active biocide HOCl. However, HOCl itself reacts with natural organic matter (NOM) through substitution reactions to produce chlorinated byproducts such as trihalomethanes (THMs).

Biocidal Efficacy

Chemical properties make a difference:

Active Agent	Oxidation Potential Volts	Oxidation Capacity Electrons
O ₃ Ozone	2.07	2 e ⁻
CH ₃ COOOH Peracetic Acid	1.81	2 e ⁻
H ₂ O ₂ Hydrogen Peroxide	1.78	2 e ⁻
NaOCl (bleach) Sodium Hypochlorite	1.49	2 e ⁻
ClO ₂ Chlorine Dioxide (AlfaSIP)	0.95	5 e ⁻

Chlorine Dioxide has less than ½ the oxidation potential of ozone, is 36% lower than bleach and 47% lower than peracetic acid. This, coupled with the fact that the activated solution does not alter the pH of the solution, translates to better compatibility with materials prone to oxidation.

Because it can gain 5 electrons, chlorine dioxide has a much higher oxidation capacity than bleach, ozone, peracetic acid or hydrogen peroxide.

Properties of Pure Chlorine Dioxide - Advantageous in Biopharmaceutical Applications

Pure gas diffusing from the surface of the AlfaSIP solution decontaminates closed vessels, even in the head space.

Rapid flushing from tanks and piping, usually in a few volumes of water. Leaves no residue nor film.

Accommodates heat-sensitive equipment that cannot currently be effectively disinfected.

Chlorine dioxide presence is easily, accurately measured using cost effective, readily available detectors or test strips.

Able to penetrate and eradicate organic matter and slime established on surfaces and lines. Permits quick and easy removal.

Not corrosive to most materials, including ultracentrifuge components, at normal use concentrations.

Generated on-site without need for capital equipment.

Easier to use than other chemical disinfecting solutions. Unused solution can normally be sent to sewer without additional treatment (check local regulations first).

Rapid Disinfection Without Heat

FREQUENTLY ASKED QUESTIONS ABOUT THE ALFASIP™-50D KIT AND PURE CHLORINE DIOXIDE, THE ACTIVE INGREDIENT

How many ultracentrifuges will a single AlfaSIP-50D kit treat?

The kit produces 50 liters of disinfecting /sanitizing solution at 100 ppm. About 5-6 liters are required to sanitize an Alfa Wassermann Continuous Flow Ultracentrifuge so one kit is enough to treat 4-5 machines before and after every run.

Once the AlfaSIP solution has been made, for how long is it usable?

The solution remains usable at the correct strength for 15 days after production from the AlfaSIP-50D kit.

What strength of solution is necessary for disinfection / sanitization?

The AlfaSIP-50D kit produces 50 liters of chlorine dioxide at 100 ppm, which requires a 10-minute disinfection protocol. The activated gas attacks S-S bonds in biological structures and little else, so smaller quantity at lower concentration is sufficient compared with many other disinfecting agents.

How about sanitization of ultrafiltration and chromatography systems?

The solution from the AlfaSIP-50D kit can be used to sanitize ultrafiltration systems. It passes through membranes (even RO) providing simultaneous disinfection on both sides. Depending upon the specific media and buffers, the AlfaSIP-50D kit can also be used to sanitize some chromatography systems. For example, Phosphate Buffered Saline, Acetate and TRIS are entirely compatible with AlfaSIP. It is always required that users first check compatibility with the manufacturer of the equipment to be sanitized.

What other uses does AlfaSIP have?

The solution from the AlfaSIP-50D kit can be used at 100 ppm to disinfect and sanitize other laboratory equipment such as centrifuges, biosafety cabinets, incubators and cold rooms. At 50 ppm strength, it is used for disinfection of the coolant loop on the AWST ultracentrifuges. At the 20 ppm level, it can be used to sanitize and clean hard lab surfaces.

Since AlfaSIP is a chlorine dioxide product, does it create or employ chlorine or oxidize by chlorinating?

AlfaSIP-50D does NOT contain nor produce chlorine, hypochlorous acid or bleach! In fact, the chemical reaction producing the chlorine dioxide prevents the production of free chlorine.

What is AlfaSIP's toxicity profile?

Results of independent toxicity tests on the activated solution (at concentrations greater than 650 ppm) included:

- Acute Oral: LD₅₀ > 5,000 mg/kg. Not considered toxic via the oral route.
- Dermal Sensitization: Not considered to be a contact sensitizer.
- Acute Inhalation: LC₅₀ > 2.07 mg/L. Not considered to be toxic via the inhalation route.
- Primary Eye Irritation: Minimally irritating to the eye.
- Primary Skin Irritation: Slightly irritating to the skin.

However, even at the application concentrations of 100 ppm or less, all precautionary measures listed on the label and technical bulletin should be followed at all times. Never swallow the solution or inhale its fumes.

Is AlfaSIP harmful to equipment?

Continuous exposure at ambient temperature (22°C / 72°F) of 304L and 316L stainless steel up to 550 ppm chlorine dioxide, in both welded and non-welded condition, is not expected to produce any discernable corrosion. Chlorine dioxide produced by the AlfaSIP-50D kit is also compatible with most plastics and elastomers. The keys are the solution's non-acidity and efficacy at comparatively low concentrations and the inherent lower aggressiveness (oxidizing potential) of chlorine dioxide compared with many other oxidizers.

Does AlfaSIP have to be neutralized at disposal?

Unlike sodium hydroxide, the AlfaSIP-50D solution does not need to be neutralized and can usually be drained into local sewers. Check first with local environmental authorities. Dispose spent envelope according to label instructions or send it with other chemicals for disposal.

What is the difference between stabilized chlorine dioxide and AlfaSIP?

The term "stabilized chlorine dioxide" is misleading. Formulations so-named contain sodium chlorite and activating agents that react to release chlorine dioxide slowly, producing low concentrations of ClO₂ at an acidic pH and containing high levels of the chlorite ion (ClO₂⁻) that remain in-solution. Because the small quantity of chlorites present in the AlfaSIP-50D envelope cannot escape into the activated solution, AlfaSIP is generally compatible with most materials, and effective in oxidizing.

Example Solution Analyses:

Stabilized ClO ₂	2.5% ClO ₂ pure	134 ppm Chlorite	pH 3.4
AlfaSIP	>99% ClO ₂ pure	0.6 ppm Chlorite	pH 6.9

In what situations is AlfaSIP not appropriate?

Conditions to avoid (those which can degrade AlfaSIP):

- The presence of readily-oxidizable substances
- A pH of < 3 or > 10
- The presence of reducing agents such as NaHSO₄
- Temperatures above 35°C (95°F)

Disinfection of Lab & Processing Equipment

Simple Operation

AlfaSIP fluid is prepared 10 hours before required use and makes a 100 ppm concentration of pure chlorine dioxide in water.

An AlfaSIP-50D envelope is removed from the sealed packet and placed in 50 liters of Water For Injection (WFI) or distilled water in a sealable container, leaving outside the removal line attached to the envelope. A sticker is placed on the container to record the time and date the envelope must be removed from the reservoir – between 10 hours and 48 hours after immersion.

The concentration of ClO₂ must be checked using AlfaSIP™ Wide Range Test Strips to ensure it has achieved the target concentration level.

The solution can be used up to 15 days after activation.



General Use

AlfaSIP can be used as a disinfectant and sanitizer for stainless steel and other hard, non-porous surfaces such as tile floors, walls, ceilings, stainless steel cold rooms and walk-in incubators in the laboratory. It can also be used as a disinfectant and sanitizer for centrifuges, ultrafiltration and chromatography systems,

The suitability of pure chlorine dioxide for a specific instrument should always be checked with the manufacturer before use.

Disinfection / Sanitization Method for the Rotor System of an Alfa Wassermann Ultracentrifuge

Recommended for use before and after every run. Should be carried out at least every day of centrifugation using AlfaSIP at 100 ppm concentration.

After ensuring that the fluid line is free from obstruction by large particles, AlfaSIP 100 ppm solution is pumped through until the rotor and fluid lines are full of solution. Ten minutes from the end of filling, either drain and rinse the system with pure water, then switch to buffer, OR introduce buffer directly.

AlfaSIP™ Chlorine Dioxide UltraLow Range Test Strips are used to check that the level of ClO₂ has dropped to the level acceptable to the operator, or to zero concentration (non-detect) by comparing the color of the strip after immersion with a standard chart.

Disinfection / Sanitization Method for the Coolant Loop of an Alfa Wassermann Ultracentrifuge

Recommended frequency: Daily if water is used as coolant fluid or every 5-30 runs if ethylene glycol / water mixture is used as coolant fluid (more runs are permitted if they are frequent).

The coolant loop fluid reservoir is emptied and then the fluid is replaced by AlfaSIP at 50 ppm concentration, filling the reservoir to 2/3 full, pumping the fluid around the coolant loop and then leaving it for 30 minutes.

The AlfaSIP solution in the reservoir is replaced with distilled water or WFI and then flushed. AlfaSIP™ Chlorine Dioxide UltraLow Range Test Strips are used to check that the concentration of ClO₂ remaining has dropped to below the level acceptable to the operator. The water is then replaced with coolant fluid and the system flushed.

Depending on the intended use of the product, specific instructions for use will apply. Please contact the AWST application support group at applications@awst.com.

AlfaSIP-50D Kits

Sealed foil-packed kits in a 10-pack carton

AS-50D-10-EU	10 AlfaSIP-50D Kits – EU / International
AS-50D-10-US	10 AlfaSIP-50D Kits – US / N. America

AlfaSIP Test Strips

Sealed canister (one) of 50 chlorine dioxide test strips

AS-TS-WR-50	50 Wide Range Test Strips	0-500 ppm
AS-TS-UR-50	50 UltraLow Range Test Strips	0-10 ppm

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