

BackGround

The use of silver in various forms for water treatment, wound dressing/healing, neonatic treatment and other medicinal treatments reach back to ancient times. Today, forms of silver are found in functional products for water purification, bandages, algacide for pool water, integrated into fabric for medicinal benefits and numerous others. Clinical work continues for expanded applications that include acne treatment, oral rinses, toothpaste and vaginal douches.

Recent developments in silver technology have centered on stabilizing the silver in aqueous systems. This has included both colloidal silver, a suspension in water, and silver ion, which is soluble in water. Stabilized silver ion technology is the state of the art. This form of silver ion exhibits long term stability in solution, therefore is capable of providing silver's inherent performance benefits over time. One such application is the maintenance of dental operatories' treatment water. The silver ion solution is colorless, odorless, tasteless and non-caustic.

Biofilms and Dental Treatment Water

Dental treatment water quality has been a topic of discussion for several years. Inclusion into the Center for Disease Control Guideline for Infection Control in Dental Health-Care 2003 resulted in the adoption of this water quality standard by many states and has clearly defined the standard of care for dentistry.

Dental Unit Water Quality

The following excerpt is from the CDC *Guidelines for Infection Control in Dental Health-Care 2003*.

Research has demonstrated that microbial counts can reach $\leq 200,000$ colony-forming units (CFU)/mL within 5 days after installation of new dental unit waterlines (305), and levels of microbial contamination $\leq 10^6$ CFU/mL of dental unit water have been documented (309,338). These counts can occur because dental unit waterline factors (e.g., system design, flow rates, and materials) promote both bacterial growth and development of biofilm.

Although no epidemiologic evidence indicates a public health problem, the presence of substantial numbers of pathogens in dental unit waterlines generates concern. Exposing patients or DHCP to water of uncertain microbiological quality, despite the lack of documented adverse health effects, is inconsistent with accepted infection-control principles. Thus in 1995, ADA addressed the dental water concern by asking manufacturers to provide equipment with the ability to deliver treatment water with ≤ 200 CFU/mL of unfiltered output from waterlines (339). This threshold was based on the quality assurance standard established for dialysate fluid, to ensure that fluid delivery systems in hemodialysis units have not been colonized by indigenous waterborne organisms (340).

Standards also exist for safe drinking water quality as established by EPA, the American Public Health Association (APHA), and the American Water Works Association (AWWA); they have set limits for heterotrophic bacteria of ≤ 500 CFU/mL of drinking water (341,342). Thus, the number of bacteria in water used as a coolant/irrigant for nonsurgical dental procedures should be as low as reasonably achievable and, at a minimum, ≤ 500 CFU/mL, the regulatory standard for safe drinking water established by EPA and APHA/AWWA.

Maintaining Clean Water

ConFirm Monitoring Systems, Inc has developed a safe and effective solution to this specific problem; BluTab is an effervescent tablet that is designed to be used as a dosage or continuously present treatment product, which will maintain the DUWL water quality. BluTab is simply added to an empty self-contained water bottle before each filling and provides 1 ppm of the stabilized silver ion in DUWLs.

Safety

The EPA RED of 1992 for silver refers to elemental silver in various forms, for instance silver nitrate. The document includes a human health assessment section whereby the usual required toxicity and exposure studies were waived due to the adequate understanding of well documented and published silver safety information. It is noted in animal toxicology studies that elemental silver is considered Category III (relatively low acute toxicity) for oral and dermal toxicity and Category IV (non-irritating) for eye and skin irritation. Further it is stated not to be a skin sensitizer nor is it known to have human carcinogenic potential. It is important to consider that this form of silver refers not to the ionic form, but to the more historical forms and uses of silver. This reference offers guidance in a general context for the overall safety assessment of silver.

The recent development of the stabilized ionic form of silver has been well tested for safety. To determine the toxicity and safety risk of an individual chemical or a blend of chemicals as well as finished products, standardized acute toxicity testing is widely accepted. This battery of tests is used extensively for the chemical, consumer goods and pharmaceutical industries to assess toxicity potential for decades. The results of the toxicity safety testing for the silver ion solutions are summarized in Table I as follows:

TABLE I:

<u>Toxicity Test</u>	<u>Silver Ion Concentration</u> (1ppm (1 mg/liter))
Acute Oral:	>5000 mg/kg.
Skin Irritation:	Non-irritating
Eye Irritation:	Non-irritating
Acute Dermal LD50 (rat):	>5000 mg/kg.
Dermal Sensitization:	Not a contact sensitizer
Carcinogenicity:	Not listed by ACGIH, IARC, NIOSH, NTP or OSHA

The EPA has established a reference dose (RfD) for many elements and chemicals including silver. The EPA defines the RfD as the amount that the most sensitive individuals may ingest every day of a 70 year lifetime without the likelihood of harm. It is reasonable to say this is an extremely conservative safety assessment. The RfD for silver ingestion is 0.005 mg/kg of body weight per day. A practical illustration of this measure is: a 70 kg. (154 pounds) person may ingest 350 mls every day for 70 years without exceeding the RfD and thus, even the most sensitive of individuals, would not be harmed. With regard to the application for DUWLs, a use level of 1 ppm would not expose a patient to the EPA RfD for silver. A typical dental patient will be exposed to between 50-200 mls of water (BluTab provides >1 ppm ionic silver (>1 mg/liter) during a visit. Almost all of this water exposure will be suctioned away before a patient ingests it. Assuming they could ingest up to 10% of the maximum typical amount this accounts for the ingestion of 20 mls. At a concentration of 1 ppm silver, this would expose the patient to 0.02 milligrams of silver in a single visit, that is, well below the RfD. To put this in perspective, an average sized person (154 pounds) ingesting 20 mls or .02 milligrams is actually exposed to one-twentieth of the amount that the most sensitive individuals may ingest **every day** of a 70 year lifetime without the likelihood of harm.

Silver Ion Applications and In-Use Safety Assessment

ProEdge Dental Products
7042 S. Revere Pkwy. Ste. 400
Centennial CO 80112

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ConFirm Monitoring Systems, Inc.
109 East Inverness Drive, Unit F
Englewood, Colorado 80112