

Government Reports on Colloidal Silver

U.S. Environmental Protection Agency (EPA) Reference Dose for Silver

"The EPA publishes a reference dose (Rfd) for silver which is an estimate of daily exposure to the entire population that is unlikely to be associated with a significant risk of adverse effects over a lifetime. The current Rfd for oral silver exposure is 5 micrograms/kg/day with a critical dose estimated at 14 micrograms/kg/day. Based on this Rfd, a 150 pound adult should not exceed 350 micrograms/day." Argyria is caused by the same mechanism that is used when developing photographs. It is the same thing. If you start with a salt of silver, and expose it to light, some of it will reduce to silver metal. Then if you have a developer (caffeine is a good developer) in an alkaline solution (blood is normally alkaline), additional silver will plate out from the compound onto the metallic particles, making them grow. That is the photographic process, and that is how one gets Argyria.

Now, the process requires silver salts. There are no substitutes. Colloidal silver contains no silver salts. Basically silver salts are what are in unexposed film. Silver colloid is what is in a developed photograph. If you put a developed photo into the sun what does it do? It fades, it doesn't turn darker. That is because a developed photo has no silver salts to add to the silver particles since it is already nothing but reduced silver particles. Thus colloidal silver cannot cause Argyria. Theoretically I guess one could take CS with sufficient ppm and in sufficient quantity to cause aggregation, but one would likely drown from too much water first, as the amounts would be truly phenomenal. In years of pouring over hardcopy of obscure medical cases no one has yet found a single report of any adverse reaction to very fine particles of very fine silver floating in very pure water.

FDA could find no adverse events

- ◆ No Reported Deaths
- ◆ No Allergic reactions
- ◆ No harmful drug interactions
- ◆ No cases of Argyria from colloidal silver made with AC or DC

(Please read both of the following letters, the first is the request and the second the FDA's response)

The Request

Food and Drug Administration
U.S. Department Of Health and Human Services
Public Health Service
5600 Fishers Lane
Rockville, MD 20857

Dear Sirs/Madam,

Pursuant to the Freedom of Information Act and in regard your August 17th, 1999 ruling regarding colloidal silver, could you please supply the following documentation on which you based your decision?

1. The number of deaths related to the consumption of colloidal silver.
2. The number of allergic reactions to the consumption of colloidal silver.
3. The number of harmful drug interactions from both OTC and prescription drugs when combined with colloidal silver.
4. The number of reported cases of Argyria from colloidal silver made with the AC or DC electrical process.
5. The number of cases of Argyria from colloidal silver that did not contain protein stabilizers.

Thank you for your time and consideration of this request.

Sincerely,

Brent Finnegan

The FDA response:

Public Health Service
Center for Drug Evaluation and Research
Office of Training and Communication
Freedom of Information Staff HFD-205
5600 Fishers Lane 12 B 05
Rockville, Maryland 20857
DEPARTMENT OF HEALTH AND HUMAN SERVICES
November 3, 1999
In Response Refer to File: F99-22589
Brent Finnigan Takoma (sic), WA 98408

Dear Mr. Finnigan:

This is in response to your request of 10/14/99, in which you requested adverse events associated with the use of Colloidal Silver. Your request was received in the Center for Drug Evaluation and Research on 10/25/99. We have searched the records from FDA's Adverse Event Reporting System (AERS) and have been unable to locate any cases that would be responsive to your request.

Charges of \$3.50 (Search \$3.50, Review \$0, Reproduction \$0, Computer time \$0) will be included in a monthly invoice.

DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.

If there are any problems with this response, please notify us in writing of your specific problem(s).

Please reference the above file number.

Sincerely,

Hal Stepper
Freedom of Information Technician
Office of Training and Communications
Freedom of Information Staff, HFD-205

Silver—Safety and Efficacy

Quoting from Alexander G. Schauss, Ph.D. (John Hopkins University)

“...you should be advised that we recently completed an extensive review of the scientific literature on the safety of silver, especially as it relates to its one known potential side effect, namely, Argyria. Argyria is an irreversible discoloration of the

pigment (skin) caused by excessive silver intake or chronic exposure to silver by certain tissues. The amount of silver required to develop Argyria is estimated to be 3.8 grams per day. By comparison standard 10 ppm colloidal silver contains silver in amounts equaling less than 1 milligram of silver (1,000 micrograms = 1 milligram; 1,000 milligrams = 1 gram), which therefore represents an amount approximately 1/500th to 1/1000th of the amount of silver considered to be a risk in the development of Argyria.

Most cases of Argyria reported in the medical literature over the last 100 years involved chronic intravenous or intramuscular use of the silver preparations, most often involving a silver drug prescribed by physicians which in most cases contained silver nitrate. Other cases of Argyria reported in the medical literature involve application of silver preparations used for many months or years in the treatment of the eye or vagina for certain diseases. We could not locate a single case of orally consumed colloidal silver manufactured in the last 25 years causing Argyria in our review of the literature. This is probably due to the low levels of silver contained in such preparations, since only very small amounts of silver are needed for its antiseptic effect. Humans consume approximately 100 micrograms of silver every day in the diet. Additional amounts within this range would be considered safe by all reasonable estimates, especially if the amount needed to develop Argyria would be equivalent of 380,000 micrograms (or 3.8 grams) of silver a day.

As for the efficacy of silver preparations, we found considerable scientific evidence published over the last 75 years that a number of silver compounds can be effective germicidal (antiseptic) agents against several hundred pathogenic organisms. However, silver is not termed an antibiotic as some have claimed because an antibiotic by definition is derived from a living organism.

Sincerely,
Alexander G. Schauss, Ph.D.
Director, Life Sciences Division
John Hopkins University

Alexander G. Schauss, Ph.D., is the Director of the Life Sciences Division of the American Institute for Biosocial Research, Inc. in Tacoma, WA. He is a member of the Government's Commission on Dietary Supplements. He holds joint faculty positions as Associate Professor of Research and Senior Director of Research and Development at the Southwest College of Naturopathic Medicine and Health Sciences, in Tempe, AZ., and, as Associate Professor of Behavioral Sciences at the National College of Naturopathic Medicine in Portland, OR.

Dr. Schauss is an Emeritus Member of the New York Academy of Sciences, former Chairman of the Food Policy Council of the National Council for Public Health Policy, Founding Member of the British Society of Nutritional Medicine, Emeritus Executive Director of the American Preventive Medical Association, Emeritus Executive Director and current President of Citizens for Health, and a member of the American Public Health Association and the American Association for the Advancement of Science.

Herxheimer Reaction

The only negative effect reported by CS users is a phenomenon called the “Herxheimer effect”, named after Doctor Karl Herxheimer (who identified this phenomenon). Sometimes, when a person starts off for the first time ingesting a large amount of CS, the CS is so efficient at killing pathogens in the body that the body cannot adequately dispose of the dead pathogens through the normal eliminative organs, and it resorts to the secondary ones, the lungs, sinuses and skin. Or the CS user may experience diarrhea, as the body tries to flush itself out. In that case, one merely needs to reduce or temporarily stop the CS until the healing crisis is over, and then start taking smaller amounts of CS.

U.S. Environmental Protection Agency (EPA) Poison Control Center and Center for Disease Control (CDC) both conclude: *Colloidal Silver is Harmless*

A new European Union Drinking Water Standard in draft form has removed any limitations on silver in drinking water following the World Health Organization’s “Guidelines for Drinking Water Quality” which states, "It is unnecessary to recommend any health-based guidelines for silver as it is not hazardous to human health." According to the U.S. Environmental Protection Agency (EPA) Poison Control Center, CS is considered harmless. Dr. Samuel Etris, a senior consultant at the Silver Institute, says there have never been any allergenic, toxic or carcinogenic reactions to CS. The U.S. Government’s Center for Disease Control confirmed that fact in 1995.

The term Argyria describes the condition of a bluish gray color of the skin, and Argyrosis the bluing of the eye white, resulting from the use of SILVER COMPOUNDS. To better understand the misconception regarding Argyria, I will quote from the book "The Micro Silver Bullet"™ by Dr. M. Paul Farber 1996 page XII (ISBN 1-887742-00-X) In reference to a "Journal of American Medical Association" article, October 18 1995, volume 274 # 15, where cases of Argyria were cited to have been caused by silver compounds (not colloidal silver, but silver mixed with other metals), note: "These Case history presentations represent biased and unprofessional writing. The author's apparent inability to understand the difference between a silver nitrate, sulfide, or other silver compound demonstrates their lack of understanding of basic chemical properties. The matrix, substrate, and particle size are all critical to the varied functions and reactions with use of these products. That is why there has not been a single case of Argyria from a properly manufactured modern-day colloidal silver product. The cases of Argyria reported in the 1920's and 1930's resulted because the technology of the day was unable to produce a pure colloidal silver product with a small enough particle size." Ref. (4-A) The reported cases of Argyria usually involved very high and frequent doses over extended periods of time of silver salts/compounds such as silver sulfate, silver nitrate, silver chloride, etc.

The Environmental Protection Agency's Poison Control Center reports no toxicity listing for Colloidal Silver; it is therefore considered harmless in any concentration. However all of the silver salts are identified as toxic, although the only adverse effect noted is Argyria. Therefore the concern is with silver salts not Colloidal Silver. Dr John Hill D.C. in his book "Colloidal Silver, A Literature Review" states this: "Critics of colloidal silver sometimes state that it has been known to cause organ damage, kidney damage, pulmonary edema, atherosclerosis and death. "These claims appear to be based on a research study on dogs in which the dogs were deliberately killed by extremely large lethal doses of silver. At the doses given, any heavy metal and probably many essential minerals like zinc, iron, copper, etc. would have produced death in similar fashion." And again "We know that dogs died from injections of a type of protein-bound silver in dosages ranging from 500 mg to 1.9 grams of silver depending on the frequency of administration. This was equivalent in silver content to giving [per day] a 150 pound adult between 150 liters and 570 liters of 10 ppm colloidal silver, or between 75 and 285 liters of 20 ppm colloidal silver or between 50 and 190 liters of 30 ppm colloidal silver. The 10 gram estimated lethal dose for humans from Goodman and Gillman is equivalent to 1000 liters of 10 ppm colloidal silver." In another case an individual ingested an estimated 124 grams of silver nitrate over a 9-year period. She developed Argyria and an assortment of neurological symptoms as well... This report is often used by critics to attribute neurological disorders to silver consumption. They curiously fail to put in perspective the gross difference between the quantities of silver involved."

History of Silver Use for Health

"Silver has been used for centuries to prevent and treat a variety of diseases, most notably infections. It has been well documented that silver was used in ancient Greece and Rome as a disinfectant for water and other liquid storage. Silver coins were placed in the jars of liquid to maintain sterility. The American

Settlers (1800's) routinely place a silver dollar in barrels of liquids to avoid spoilage and more recently NASA has used silver to maintain water purity on the space shuttle. The free silver ion or radicals are known to be the active agents of anti-microbial silvers. Of interest are its extremely potent antibacterial properties, as only 1 part per 100 million of elemental silver is effective in a solution. Silver ion kills micro-organisms instantly by blocking the respiratory enzyme system (energy production) while having no negative effect on human cells.

In 1834 the German obstetrician F. Crede used a 1% silver nitrate solution as eye drops in newborns, eliminating blindness caused by post partum eye infections. Numerous studies in the early 1900's correlated low plasma silver levels with infections, suggesting silver to be an essential micro mineral requiring replacement. Of significant importance is that no known BACTERIAL RESISTANCE has developed to the silver ion

as opposed to current antibiotics. Charged silver solutions (electro-colloidal) were approved in the 1920's by the FDA for use as an antibacterial agent.

In addition to its recognized antibacterial properties silver solutions, especially (electro-colloidal elemental silver) were reported to improve the healing of "indolent wounds" and in the regeneration of damaged tissue unrelated to its effects on infection. The description of decreased rubor in wounds indicates an anti-inflammatory property of silver. Silver is completely non-toxic to local tissues and painless upon application. This response must be distinguished from the response of silver salts, many of which are caustic to tissues, especially silver nitrate, due to the potent oxidizing or cell damaging effects of nitrate or nitrite. Virtually all of the reports on the use of the pure elemental silver to control infection or to increase healing occurred prior to the 1940's after which antibiotics became prevalent, decreasing the use of silver (except in burns). With the recent introduction of a pure silver delivery system for use in burns and wounds, new data is being obtained which verifies these historical concepts. Silver was commonly worn in the Greco-Roman period because of its perceived qualities of "maintaining health".

<http://www.burnsurgery.org/Betaweb/Modules/silver/section1.htm>

Authors: *Robert H. Demling, M.D., Leslie DeSanti, RN, Dennis P. Orgill, M.D. PhD.*

WHAT ARE THE BIOLOGIC PROPERTIES OF SILVER RELATED TO WOUND INFECTION CONTROL AND HEALING? (THE FACTS ABOUT SILVER)

Silver has long been known to be a potent antimicrobial agent and its beneficial effects on wound biology have in general been overlooked until recently. A description of what silver does and its role in wound management will be presented briefly with a more complete discussion in later sections.

ANTIMICROBIAL PROPERTIES:

The antimicrobial activity of silver ion is well defined. Silver ion rapidly kills microbes by blocking the cell respiration pathway. The speed of action is almost instantaneous once the silver reaches the microbe. The efficacy of microbe killing is based not only on the amount of silver ion present, but likely also the presence of other silver radicals generated by a silver releasing product. Because of mechanism of action, microbial resistance to silver itself has not been reported. In addition, silver has repeatedly been shown to be non-toxic to human cells. Toxicity occurs from the complexes used to deliver silver such as nitrate and sulfadiazine.

IS SILVER TOXIC TO HUMAN TISSUE?

There are two well-described (but often inappropriately interchangeable) forms of silver toxicity. One is due to silver itself and the second more severe complication is due to the attached compound.

SILVER ION TOXICITY

(Systemic)

Although absorbed silver interacts with other metals and tissue proteins, these interactions do not appear to be harmful with the exception of the skin discoloration known as ARGYRIA, a cosmetic problem. Argyria is a process of silver granule deposition in skin leading to a permanent blue/gray discoloration. There is no tissue injury. The effect is a cosmetic problem. The most common causes were not from medicinal use of silver but rather the constant exposure to silver either as a chemist, silver miner or long term use of silver cups, plates, etc. Of interest is the fact that the term "blue blood" used to describe Royalty came from the finding of mild Argyria in European nobility from the constant use of silver place setting, silverware, and silver cups, along with the frequent ingestion of ground-up silver metal powder (used as a microbial medicine), leading to a bluish skin color. Silver granules can be found in all organs including the skin indicating that the silver aggregates are not cleared. It would therefore appear that any form of silver if given in large quantity can be a causative factor (at least 10 grams needs to be absorbed).

Silver itself has been shown to be harmless to normal human tissue. The toxicity results from the salt or complexes that are used to deliver the silver. A pure silver delivery would be the ideal approach to avoid local toxicity. (J Burn Care Rehabilitation 1999; 20:195-200)