Safety Information Related to Nanoscalar-Oligodynamic Silver Ions
A Nutraceutical Silver Supplement

Silver Safety Perspectives

Generally speaking, the *metal* minerals form a unique category of nutraceuticals and nutritional supplements because of their benefits and their parameters of toxicity. Calcium, Chromium, Cobalt, Copper, Iron, Magnesium, Manganese, Molybdenum, Vanadium, Zinc, etc… are all *metal* minerals that have proven benefits, and also known toxicity thresholds.

Silver is a trace element that is also a metal mineral. On the Periodic Table it is actually a "transitional" metal mineral that has not been declared essential to the diet. Interestingly, silver is documented to form part of our normal diet.♦ Estimates suggest that we typically ingest of from 22 to 88 mcg per day.[26, 27] In fact, our body is normal composed of approximately 1,000 mcg (1 mg) of silver.[28] Silver, although a rare element, has an average abundance of about 0.1 ppm in the earth's crust, and generally 0.3 ppm in the soil. Silver is released into our air and water through natural processes.[29]

Although silver has no declared value as determined by the National Academy of Sciences (NAS), it is important to recognize that in many cases metal minerals took long time periods to be *officially* recognized for the critical roles in human health. In the most recent past, this hiatus endured for several decades for a short list of trace metal minerals. For example, no declared human daily value (DV) existed for Chromium, Fluorine, Manganese, Molybdenum, and Selenium, for up to several decades, even though these minerals had the strongest scientific evidence of proven value or were even known to be essential during their pre-NAS recognition.[30]

Furthermore, providing that delivery of Ag^{+} to the trouble spots is accomplished, the minimal effective dosage level of pure Ag^{+} is essentially medically benign to human cells.♦[31, 32] Pure, oligodynamic silver, therefore, has its unique benefit and safety index, just as any other essential metal mineral supplement has its own benefit and safety index.

As you will see, in the ranges provided in each and every bottle of Natural-Immunogenics Corp.'s product (Sovereign Silver – 10 ppm), it is quite difficult, in fact nearly impossible within any practicality, to overdose. As labeled, it forms a prudent way to insure that dietary intake attains that suggested by previous studies that revealed silver is apart of our normal dietary intake, since trace mineral depletion in produce world-wide is a growing concern.♦[33, 34, 35, 36, 37] Therefore, taking trace mineral supplements, such as Natural-Immunogenics Corp. products as labeled, may help counter this trace mineral depletion trend.♦

From a historical perspective (circa 1930's), the average raw (elemental) silver content of the older pharmaceuticals was 10% to 25% or more. Whatever the total content of raw (elemental) silver attained in any product, the level of active (oligodynamic) silver generally never exceeded from 2% to 5%.♦[38] In other words, due to the inferior methodologies of the day, the production of active silver could only be attained and derived from large quantities of inactive silver being stuffed into the formulation, thus creating an equilibrium for a small amount of active silver to be dispersed throughout the bottle, if at all. From this disadvantage of high - inactive silver content - these products did rarely cause a permanent bluish-gray discoloration to the skin, a medical condition termed argyria, which is otherwise medically benign and harmless. Only an estimated total of 365 documented cases of argyria occurred after millions of patients were treated over many decades.[39] However, argyria continues to be reported, perhaps due to the inferior silver solutions deriving from crude home-made generators, wherein unsuspecting customers take this inferior grade product in high amounts, every day for several years.

Our products range from just 0.0001% to 0.00023% raw (elemental) silver, but with nearly 90% *active* silver present. Now compare this to the 10% to 25% or more raw (elemental) silver of inactive formulations, such as mild silver protein.

Natural-Immunogenics Corp.: *Active vs Inactive Silver*

Additionally, Natural-Immunogenics Corp. product is fundamentally all *active* silver, because we create it exclusively by an electrolytic process that makes our particles only when we provide elemental silver with a positive charge. Although fundamentally this type of process was first discovered in the late 1800's, our method perfects this original process so that our particles average 8 angstroms each, and are nearly all net positively charged, thus rendering an incredibly dispersed oligodynamic silver. In other words, our manufacturing process is so precise that we cannot make our silver particles that are net neutral in charge. Our active silver ingredient is stable for over 3 years in the bottle. If it did not maintain its positive charge, our product could not maintain its dispersion in pure water; it would clump together into larger, *inactive* silver particles. This is why it easily provides all the benefits of the higher *inactive* silver products that only deliver small amounts of active silver.

We additionally increase our product's silver activity by way of our product's attainment of an extremely high total surface area. In fact, for each cubic centimeter of elemental silver used, our manufacturing methods attain a total surface area of over 6 square kilometers.

The result is a product that achieves an activity factor for silver by way of:

1. the resulting surface area (SA) and adsorption (the pre-requisite to all absorption potential) attained for exposure *upon* biological milieus. Sovereign Silver SA, when calculated from an original source of a 99.98% cubic centimeter of pure silver, will attain from *6 to 60 square kilometers* of surface!
2. an SA that achieves great orders of magnitude of total surface *energy* (SE - the key principle to a substance's thermodynamic energetics),

3. an oligodynamic - positively charged - silver particle (ready for work),
4. a free radical-like energy effect benign to higher life forms, which is phenomenologically indeterminant[40] (i.e., in essence quantum in nature) in part because the associated Brownian movement that achieves great rapidity approximating an unprecedented Particle Diffusion Coefficient (PDC) of 10^{-5} cm^2/second,[41] and additionally in part because
5. the absorption, penetration, and delivery of the active silver *into* biological milieus (i.e., intracellular, intra-nuclear?), where it may best serve useful immune functions by way of the SA, the SE and PDC.

Adverse Event Data

1. CRC Handbook of Chemistry and Physics: 80th Edition, ed. by David R. Lide, CRC Press, Boca Rotan, FL, 1999-2000.

a. Section 4-27; Properties of the Elements and Inorganic Compounds

i. "While silver itself is not considered toxic, most of its salts are poisonous."

ii. "Silver has germicidal effects and kills many lower organisms effectively without harm to higher animals."

2. Fung, M.C., Bowen, D.L., "Silver Products for Medical Indications: Risk-Benefit Assessment," Clinical Toxicology, 34(1), 119-126, 1996. LOAEL Threshold

a. "Based on the current Rfd, for a 5 kg infant to a 70 kg adult, the maximal daily silver exposure should be less than 25-350 µg/d."

b. "However, a regular daily diet may contain up to about 90 µg of silver as a background level exposure."

c. "Some researchers have suggested that Vitamin E or selenium deficiency may increase susceptibility to systemic silver toxicity. Wagner et al. and Bunyan et al. have shown that hepatic necrosis can be induced by administering silver preparations to Vitamin E/selenium deficient rats. They hypothesized that toxicity was due to a silver-induced selenium deficiency that inhibits the synthesis of the seleno-enzyme glutathione peroxidase. Further, Bunyan et al. showed that if rat diets were supplemented with selenium or Vitamin E, exposure to silver as high as 140 mg/kg/d was still well tolerated."

3. <u>e-Medicine Journal</u>, November 2, 2001; Number 11

a. "Argyria results from prolonged contact to or ingestion of *silver salts*. It produces a gray to gray-black staining of skin and mucous membranes produced by silver deposition. Silver may be deposited in the skin either from industrial exposure or as a result of medications containing *silver salts*."

4. <u>ATSDR</u> – Agency for Toxic Substances and Disease Registry Toxicological Profile for Silver – CAS# 7440-22-4, Dec. 1990.

a. 1.4 No studies of cancer or birth defects in animals from eating, drinking, or breathing in silver compounds were found. Therefore, it is not known if these effects would occur in humans. One study of animals drinking silver compounds mixed with water for most of their life found no effect on fertility. Another study found reproductive tissues were damaged in animals after they received injections of silver nitrate. However, the tissues recovered even while the animals received more injections of silver nitrate. Tests in animals show that silver compounds are likely to be life threatening for humans only when large amounts (that is, grams) are swallowed and that skin contact with silver compounds is very unlikely to be life threatening.

b. 1.5 Studies in rats show that drinking water containing very large amounts of silver (2589 parts of silver per million parts water, or about 2.6 grams per liter) is likely to be life threatening.

d. 2.2.1. **Inhalation Exposure:**

2.2.1.1. <u>Death</u> – No studies were located regarding death in humans or animals after inhalation exposure to silver or silver compounds.

2.2.1.2. <u>Systemic Effects</u> – No studies were located regarding cardiovascular or musculoskeletal effects in humans or animals after inhalation exposure to silver or silver compounds.
<u>Respiratory Effects</u> – Occupational exposure to silver dusts can also lead to respiratory irritation (Rosenman et al. 1979, 1987).
<u>Gastrointestinal Effects</u> – Abdominal pain has also been reported by workers exposed to silver nitrate and oxide in the workplace (Rosenman et al. 1979).
<u>Hematological Effects</u>- Blood counts were reported to be normal in all individuals observed in the occupational study of silver-exposed workers conducted by Rosenman et al. (1979) with the exception of one individual with an elevated hemoglobin level.
<u>Hepatic Effects</u> – A study that measured levels of several liver enzymes (alanine transferase, aspartate amino transferase, gamma glutamyl transferase, and alkaline phoshpatase) found no significant differences between workers exposed to silver and

insoluble silver compounds and those with no history of silver exposure (Pifer et al. 1989).

Renal Effects – Studies in animals have focused only on the deposition of silver in the kidney following oral exposure (Olcott 1947, 1948) and renal tests were not conducted.

Dermal/Ocular Effects – Skin and ocular burns, caused by contact with silver nitrate, have been reported in workers (Moss et al. 1979, Rosenman et al. 1979).

2.2.1.3. Immunological Effects – No studies were located regarding immunological effects in humans or animals after inhalation exposure to silver or silver compounds.

2.2.1.4. Neurological Effects - No studies were located regarding neurological effects in humans or animals after inhalation exposure to silver or silver compounds.

2.2.1.5. Developmental Effects - No studies were located regarding developmental effects in humans or animals after inhalation exposure to silver or silver compounds.

2.2.1.6. Reproductive Effects - No studies were located regarding reproductive effects in humans or animals after inhalation exposure to silver or silver compounds.

2.2.1.7. Genotoxic Effects - No studies were located regarding genotoxic effects in humans or animals after inhalation exposure to silver or silver compounds.

2.2.1.8. Cancer Effects - No studies were located regarding cancer effects in humans or animals after inhalation exposure to silver or silver compounds.

e. 2.2.2. **Oral Exposure**

2.2.2.1. Death – No studies located regarding death in humans following oral exposure to silver or silver compounds.

2.2.2.2. Systemic Effects – No studies located regarding respiratory, gastrointestinal, hematological, musculoskeletal, hepatic, or renal effects in humans or animals after oral exposure to silver or silver compounds.

Cardiovascular Effects – No studies were located regarding cardiovascular effects in humans following oral exposure to silver or silver compounds.

Dermal/Ocular Effects – Gray or blue-gray discoloration of the skin has been observed in individuals that have ingested both metallic silver and silver compounds in small doses over periods of months to years.

2.2.2.3. Immunological Effects - No studies were located regarding immunological effects in humans following oral exposure to silver or silver compounds.

2.2.2.4. Neurological Effects – Several reports describe the deposition of

what are assumed to be silver containing granules in tissue of the central nervous system.

2.2.2.5. Developmental Effects - No studies were located regarding developmental effects in humans after oral exposure to silver or silver compounds.

2.2.2.6. Reproductive Effects - No studies were located regarding reproductive effects in humans after oral exposure to silver or silver compounds.

2.2.2.7. Genotoxic Effects - No studies were located regarding genotoxic effects in humans after oral exposure to silver or silver compounds.

2.2.2.8. Cancer - No studies were located regarding cancer effects in humans after oral exposure to silver or silver compounds.

e. 2.2.3. **Dermal Exposure**

2.2.3.1. Death - No studies were located regarding death in humans following dermal exposure to silver or silver compounds.

2.2.3.2. Systemic Effects – No studies were located regarding respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, hepatic, renal, or ocular effects in humans or animals after dermal exposure to silver or silver compounds.

Dermal – Medical case histories indicate that dermal exposure to silver or silver compounds for extended periods of time can lead to local skin discoloration similar in nature to the generalized pigmentation seen after repeated oral exposure. However, the amount of silver and the duration of time required to produce this effect cannot be established with the existing information (Buckley 1963; McMahon and Bergfeld 1983).

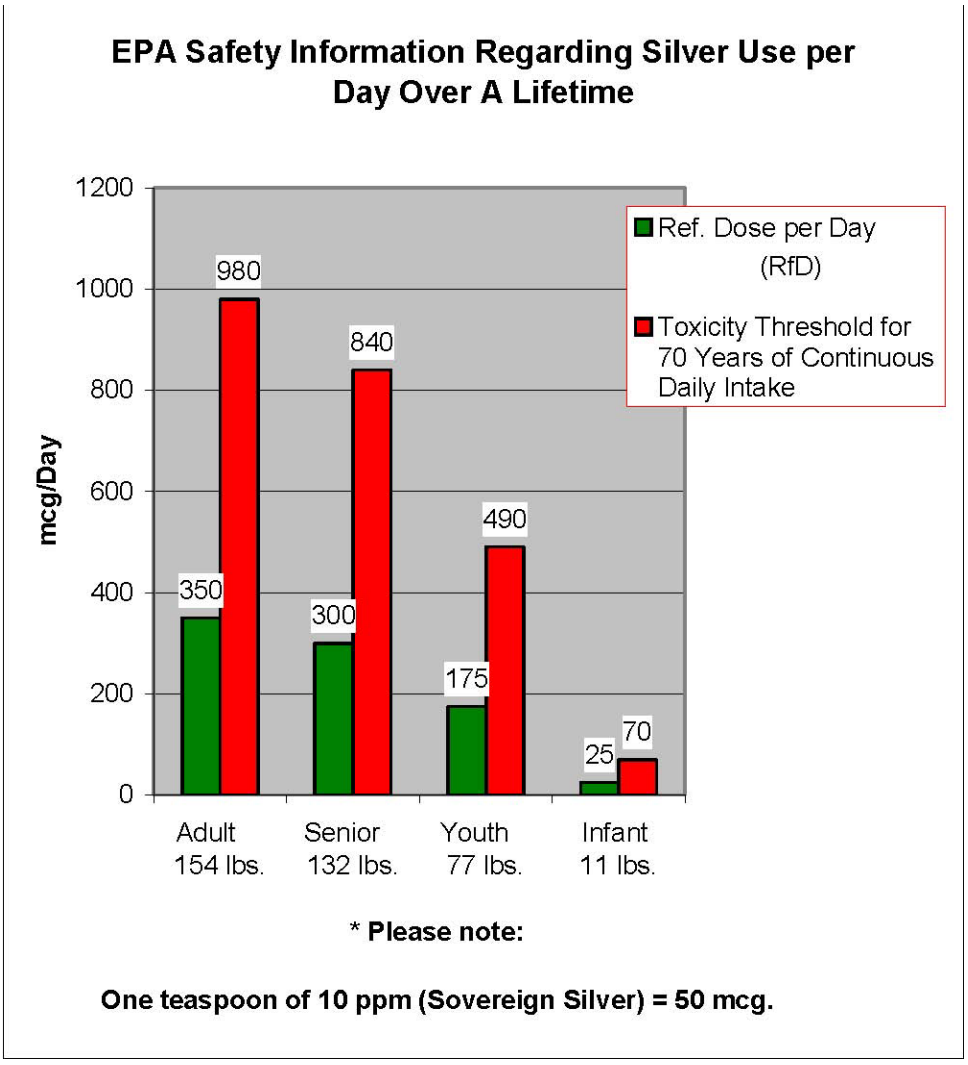
2.2.3.3. Immunological Effects – Medical case histories describe mild allergic responses attributed to repeated contact with silver and silver compounds (Catsakis and Sulica 1978; Heyl 1979; Marks 1966). Sensitization occurred in response to contact with powdered silver cyanide, radiographic processing solutions, and apparently to silver in dental amalgam.

No studies were located regarding the following health effects in humans and animals after dermal exposure to silver and silver compounds.

2.2.3.4 Neurological Effects
2.2.3.5 Developmental Effects
2.2.3.6 Reproductive Effects
2.2.3.7 Genotoxic Effects

2.2.3.8 Cancer

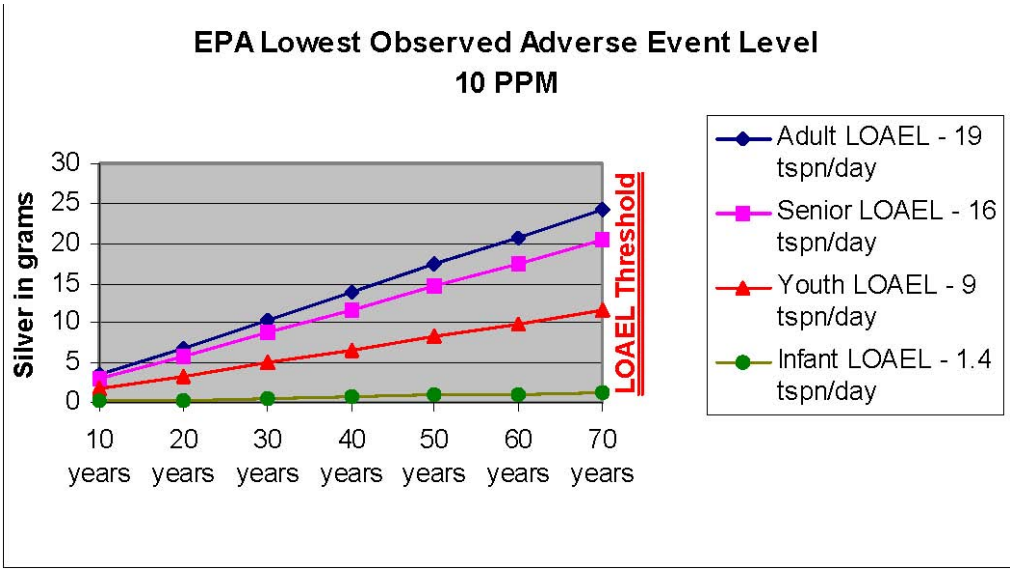
5. Environmental Protection Agency (EPA)/IRIS CASRN 7440-22-4 (It should be noted that the individuals tested in these case studies are members of a subpopulation of unhealthy adults.)



* * *

10 ppm for Adult: a.) 7 teaspoons can be taken a day for 70 years in accordance with the reference dose

b.) 19 teaspoons can be taken a day for 70 years while remaining under the critical dose of 25 grams in a lifetime



According to the EPA Dietary Silver Intake (10 ppm)

a. Taking 38 tspn daily of SS for 35 years falls below LOAEL threshold for an adult
b. Taking 76 tspn daily of SS for 17 years falls below LOAEL threshold for an adult
c. Taking 170 tspn daily of SS for 8 years falls below LOAEL threshold for an adult
d. Taking 304 tspn daily of SS for 4 years falls below LOAEL threshold for an adult
e. Taking 608 tspn daily of SS for 2 years falls below LOAEL threshold for an adult
f. Taking 200 Tbspn daily of SS for 2 years falls below LOAEL threshold for an adult
g. Taking ¾ gallon daily of SS for 2 years falls below LOAEL threshold for an adult

* * *

6. Pilcher, J.D., Sollmann, T., "Organic, Protein and Colloidal Silver Compounds; Their Antiseptic Efficiency and Silver-Ion Content as a Basis for Their Classification" The Journal of Laboratory and Clinical Medicine, p. 301-310, 1922

a. The practical value of the high antiseptic efficiency of silver nitrate is limited

by its side-actions: irritation and pain, astringency and corrosion. These may be largely avoided by the use of colloidal silver compounds which combine in many instances a fair degree of antiseptic action with a much smaller degree or entire absence of the irritant side-actions. The irritant and antiseptic actions of silver nitrate are due essentially to the free silver ions. The antiseptic

action of the colloidal preparations has also been attributed to the presence and liberation of low concentrations of silver-ions, the concentration being so low as to be practically nonirritant, but still sufficient to be more or less antiseptic.

b. Gros concludes that the colloidal silver preparations, notwithstanding their low concentration of silver ions, may be more efficiently antiseptic, in the presence sodium chloride, than is silver nitrate, because the silver chloride from the colloidal silver forms a finer precipitate and therefore redissolves more readily than when it is precipitated from silver nitrate (except in very dilute solutions).

7. <u>Silver in Industry</u>, edited by Lawrence Addicks, Reinhold Publishing Corporation, p. 401-429, 1940.

a. Concerning the toxicity of Ag-treated nutrients to the higher form of life, it is evident from the excellent treatise of Hill and Pillsbury that the Ag concentrations required would not be a dangerous source of argyria even when widely applied for public use. There still remains the problem of the significance of an argyrial atopy, although Hill and Pillsbury were unable to find convincing evidence that individual susceptibility enters into the development of argyria; this however does not exclude the possibility of sensitization to Ag compounds, especially when repeatedly consumed. On the other hand, silver table utensils have been used for centuries without any untoward effects; furthermore, no evidence of undesirable consequences due to consumption of Ag-treated food stuffs for extended periods of time, have been reported in Europe.

Concerning the deleterious effects Ag may have on nutrients, there is complete lack of information concerning such consequences of oligodynamic sterilization, which would be of particular interest for fruit juices preserved in this manner. It has been stated repeatedly that the preservation of the vitamin C content of fruit juices treated oligodynamically was particularly successful. Undoubtedly the Ag concentrations required for preservation, though higher than those needed for sterilization of water, are insufficient actually to cause changes in the nutrient values, with the possible exception of the different vitamins and other comparable essentials. Nothing appears to be known about Ag with vitamins, whereas an inactivation of enzymes by exposure to Ag solutions has been reported. The necessity for better information concerning these questions is evident.

In spite of the incomplete knowledge of many details involved in a more general application of the oligodynamic activity of Ag, it appears safe to state that – provided that certain difficulties in application can me mastered – Ag is an almost perfect chemical disinfectant for substances in contact with humans and animals. In contradiction to all other agents, Ag is practically insoluble in

those compounds which can occur under practical conditions.

8. Research Triangle Institute Human Health and Ecological Risk Assessment Support to the Development of Technical Standards for Emissions from Combustion Units Burning Hazardous Wastes (EPA Contract Number 68-W6-0053), 1999.

a. 7.3.18.2 Cancer Effects. No evidence of cancer in humans has been reported despite frequent therapeutic use of silver compounds over the years. Animal studies have shown local sarcomas after the implantation of foils and discs of silver (U.S. EPA, 1998).

b. 7.3.18.3 Noncancer Effects. The only clinical condition that is known in humans to be associated with long-term exposure to silver is argyria, a gray or blue-gray discoloring of the skin. Argyria was common around the turn of the century when many pharmacological preparations contained silver. It is much less common now. Today, case reports in humans have reported that repeated dermal contact with silver may in some cases lead to contact dermatitis and a generalized allergic reaction to silver (ATSDR, 1990b).

EPA has established an RfD for silver of 5.0E-03 mg/kg-d based on a LOAEL (adjusted) of 0.014 mg/kg-d, an uncertainty factor of 3, and a modifying factor of 1 (U.S. EPA, 1998). The RfD is based on a report summarizing 70 cases of argyria following use of silver medication in humans (Gaul and Staud, 1935, as cited in U.S. EPA, 1998).

An uncertainty factor of 3 was applied to account for minimal effects in a subpopulation that has exhibited an increased propensity for the development of argyria. The critical effect is cosmetic, with no associated adverse health effects (U.S. EPA, 1998).

EPA has medium confidence in the critical study used as the basis for the RfD because it is an old study and only describes patients who developed argyria; no information is presented on patients who received injections of silver and did not develop argyria. EPA has low confidence in the database because the studies used to support the RfD were not controlled studies, and low-to-medium confidence in the RfD because the RfD is based on a study using intravenous administration, which necessitated a dose conversion with inherent uncertainties (U.S. EPA, 1998).

Reference Concentration. EPA has not established an RfC for silver (U.S. EPA 1998).

9. The following studies suggest compelling evidence that silver is indeed safe and non-

toxic:

a. European Commission, <u>Scientific Committee on Food</u>: Consumer Policy and
Consumer Health Protection. CS/PM/GEN/M82 final, 6/11/2000.

Ref. # 86434 – Silver Sodium Hydrogen Zirconium Phosphate
Available: demonstration of not detectable (0.0004 mg/kg food) migration of Zr and Ag into food simulants under worst-case conditions of reflux; evidence of extensive leaching of silver from the additive into buffers containing sodium ions; two gene mutation assays in bacteria (negative; performed with Novaron AG300 (3.8% silver) and Novaron AG1100 (10% silver)), gene mutation assay in cultured mammalian cells (equivocal; performed with Novaron AG300); in vivo mouse micronucleus assay (negative; performed with Novaron AG300); acute toxicity data (performed with Novaron AG300 and Novaron AG1100); 13-week oral rat study (performed with Novaron AG300); teratogenicity study in rats (performed with an experimental mixture of Novaron); dermal toxicity (performed with Novaron AG300 and AG1100); inhalation toxicity data (performed with an experimental mixture of Novaron); eye irritation data (performed with Novaron AG300); skin sensitization data (performed with Novaron AG300).

b. US EPA FQPA (Food Quality Protection Act) Implementation Activities Registered: Sildate (silver oxide) as a disinfectant and broad-spectrum preservative. EPA registration number: 3432-64.

c. American Silver L.L.C. (ASAP Solution) – colloidal silver

An LD-50 test was performed in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500. ASAP Solution was given to a number of both male and female test rats. The amount of ASAP Solution given to the rats was 5g/kg, or the equivalent of a 200 pound man taking 192 teaspoons of ASAP 10 ppm solution at one time.
<u>Results</u>: Under the conditions of the study, there was no mortality or significant evidence of toxicity observed in the rats. The test article (ASAP Solution) would not be considered toxic at a dose of 5g/kg by oral route in the rat.

10. <u>Other Related Clinical Studies, Benefits vs Safety and Pharmacokinetics Associated</u>
<u>to the Active Ingredient (Oligodynamic Silver Ion in a Sub-colloidal Hydrosol Format) of Natural-Immunogenics Corporation's Mineral Supplements and Nutritional Products.</u>

Benefits vs Safety of Oligodynamic Ag^+ – An Overview

Preliminary clinical research into the Benefits vs Safety for certain forms of silver, which spans over 80 years with various methodologies and product formulations, demonstrate that most silver products appear to be effective over a broad spectrum of immune risks. Individual formulations have different inherent potentials for toxicity, however the key factors that *improve* a silver formulation's beneficial effects appear in many instances to be the key factors that *lessen* toxicity. These factors are:

- Stable and finely dispersed silver solutions are thought to be more effective and less toxic than silver solutions containing larger silver particle size. Emerging scientific investigations are revealing elimination routes for silver as silver ions or atoms, and these investigations suggest that elimination difficulties are proportional to the increase in silver particle size. Either silver ions as single atoms are removed through these mechanisms, or very small groups of these atoms are removed (e.g., open or chain polymer pentamers, tetramers, etc…).[42, 43, 44, 45, 46, 47]
- Larger silver particle size may be more easily deposited into tissues rather than eliminated with mechanisms better suited to handle smaller particle sizes (i.e., metallothioneins, amino acids, albumin, sulfhydryl and imidazole groups,[48] WBC – bile routes of elimination, etc).
- Finer particles, having greater surface area than larger particle sizes, offer greater intervention with infectious processes.
- Stable, pure, and fine silver particles are more likely to be eliminated first through bile and then secondly through normal kidney excretion routes.[49] As previously mentioned, the 80th edition of CRC's Handbook of Chemistry and Physics, "While silver itself is not considered to be toxic, most of its salts are poisonous… Natural silver contains two stable isotopes… Silver compounds can be absorbed in the circulatory system and reduced silver deposited in the various tissues of the body… Silver has germicidal effects and kills many lower organisms effectively without harm to higher animals."[50] Medicinal solutions of silver have no known established lethal dose (LD) or LD-50 value, although one report estimates that the lethal toxic dose (LTD) ranges between 3.5 to 35 grams for an average adult.[51] This study, however, does not specify what formulations upon which it based its conclusions (silver nitrate, silver chloride, silver arsphenamine, silver sulfadiazine, etc.). This is common to most peer-reviewed articles when presenting data on silver toxicity or argyria. It suggests that either (a) the authors are not toxicity experts with regard to silver speciation respective to the varied and diverse silver medicinals employed over the last 100 years, or (b) there is an intention to not identify these diverse silver formulations with their significantly different toxicity characteristics.
- The Agency for Toxic Substance and Disease Registry (ATSDR) does list out carefully the older varieties of different silver medicinals, and it

carefully lists the toxicities peculiar to each.[52] However, there has been no toxicity parameters covered by ATSDR for a pure oligodynamic Ag^{+} and water solution only. And to compare such a formulation to other silver medicinals would be akin to comparing apples to oranges. Indeed, top authorities such as regard such a formula to be the least toxic of all silver formulations, because it is simply pure silver and nothing else.[53, 54, 55]

- Even the most recent peer-reviewed reports on Argyria, let alone those reported in the lay press, make no distinction between toxicity differences between radically different silver formulations. For example, just the differences between the often cited older colloidal silver formulations is extraordinary: Strong Silver Protein formulations range from 7.5% to 8.5% elemental silver, while curiously Mild Silver Protein formulations range from 19% to 25% elemental silver content![56] In reality, the names were assigned because although the Strong Silver Protein formula contained less overall silver, its formulation favored the liberation of more active silver ions when administered than did the Mild Silver Protein formulations.[57]
- And the confusion surrounding toxicity can get worse in some reports.

(a) The toxicity range was extrapolated from a single murine study.

(b) Extremely rare and isolated human deaths reportedly associated with silver ingestion or infusion, have been reported. However, the circumstances of such cases were so ill-defined that it is impossible to formulate any meaningful data, let alone determine any conclusions.[58, 59, 60, 61]

(c) When authors cite the LTD, they do not identify over what time frame the silver was administered. Typical doses of silver given over typical time frames are not known to cause any problems. By typical, it is meant those reported in peer-review articles of their day. Presumably the LTD cited by recent reviewers was administered as an extraordinary large single dose over an atypical brief time period.[62]

For emphasis we re-state that the EPA/IRIS critical oral dose figure of 14.00 mcg/kg/day only applies to a continuous daily exposure period of 70 years, resulting in a cumulative dose of twenty-five (25) grams total elemental silver. Only at this point does the only known toxic symptom occur of simple argyria, with the exceptions of (i) extremely rare and typically self-limiting allergic reactions, and (ii) readily manageable Herxheimer Effects.

Dosage Consensus and Recommendations

Our label is DSHEA compliant and suggests 1 tsp or more daily of our 10 ppm product (Sovereign Silver) to be taken on an empty stomach. To best support acute immune stresses when these unexpectedly surface, an average adult may take up to 1 teaspoon every 20 or 30 minutes throughout the day of either product.♦[63, 64, 65, 66, 67, 68]

For people less concerned with recent or acute immune stresses, but very

concerned about chronic immune stresses or long term immune challenges,[69, 70, , 7172] either product offers better immune support by starting with 1 teaspoon twice daily for a week or more, and then gradually increase every three days up to 1 tablespoon twice daily. Again, it is best to take Natural-Immunogenics Corporation's products on an empty stomach.♦

Lastly, at the high end of the Benefits verses Safety, up to seven teaspoons daily may be safely taken for *extended* periods - as the EPA's Referenced Daily (RfD) dose suggests - when higher levels of immune support is needed or desired.[73, 74, 75, , , , 76777879]♦ Second, adjust for weight in younger adults and children as appropriate, typically one half the adult dose. And third, consider one teaspoon or more for general daily maintenance. Please refer to the graphs on safety and risks for further information.

However, for those people working in the silver industry or for those exposed to silver compounds regularly or for long periods, only a doctor should direct colloidal silver supplementation.

Review of Official and Unofficial Pharmacopoeia Monographs on Various Silver Preparations Including Silver Hydrosols

GENERAL BACKGROUND RELAVANT TO SILVER - It has finally become recognized that when addressing toxicity concerns over silver or silver compounds, it is the type (speciation) of silver compound that is important. There are no toxicity studies reporting adverse events with silver (i.e., argyria) that were focused exclusively on pure silver. Silver as it occurs in <u>compounds,</u> appears to be the source of all reports on silver's possible toxicity to higher life forms.[80, ,81 82]♦ One hallmark that distinguishes nutraceuticals from drugs from a physiological perspective are their degrees of toxicity. Another hallmark that distinguishes between the two from legal a perspective is that with nutraceutical preparations, it is permissible and acceptable to document benefits by citing from peer-review the pertinent, yet separate and individual *active ingredients* - so long as such citings are in (a) proper context, (b) truthful, and (c) non-misleading. In this piece-meal fashion, one by one, the documented benefits within the whole nutraceutical preparation can be claimed. An example is copper ascorbate, wherein the benefits of both copper and Vitamin C as nutrients may be claimed by the manufacturer. Providing the toxicities for either separately are not exceeded when combined, no concerns arise. Contrarily, drug preparations must show benefits exclusively from the total combined formulation. For example, synergism between two drugs within a single drug preparation would be scrutinized with the utmost care, both in terms of benefits verses safety, since degrees of toxicity may synergistically escalate through rate limiting features associated within the P-450 detoxication system.♦ Recently, great attention has been applied to nutraceuticals being ingested during rounds of drug therapy. Some drugs become more toxic when select nutrients are ingested in large quantities, or certain nutrients may become toxic due to the effects of the drugs. **However, ATSDR has specifically stated that a complete review made as of 1990, revealed no such drug-silver interaction for concern.**

With metal-based drugs as well as with metal mineral supplements, both the quantity of the active and inactive ingredients to the specific preparation as well as the form or formulation of the specific preparation are quintessential to the "speciation" of the preparation.♦ This is especially true when dealing with silver as a nutraceutical as opposed to silver being dealt with as a drug.♦ For example, in 1992 the FDA removed from their OTC monographs Mild Silver Protein, a colloidal silver compound, due to the paucity of human efficacy data as it applied to this preparation as a drug.[83] This stance may have been instigated because of the outrageous disease claims being made for such inferior silver products by several manufacturers coupled to the concern over argyria pertaining to these inferior products. As a direct result of this 1992 status-change, no approved colloidal silver products have been available OTC since 1998. Notwithstanding, high-grade oligodynamic silver hydrosols may provide an important role under the status of dietary supplements, due in part to the differing purposes, intent and uses reserved under DSHEA, in addition to the advances in technology now being employed by this company.

SPECIATION PERTAINING TO SILVER - Speciation is a term that describes the physical and chemical properties of a metal as it relates to the metal's fate, transport and toxicity. Weakly absorbed metals and metals associated with insoluble sulfides vary greatly in concerns of toxicity.♦[84] As regards pure silver or silver compounds intended for ingestion or human exposure, we already mentioned that ATSDR CAS # 7440-22-4 has found no chemicals (food or drug based), which might escalate silver's toxicity as it relates to silver speciation. Therefore, as a nutraceutical being introduced as part of the general diet, this silver hydrosol has no known synergists for concern in regards to toxicity.

PERSPECTIVES ON BENEFIT VS TOXICITY AS IT PERTAINS TO SILVER SPECIATION - The speciation of silver is finally gaining a wider understanding among medical toxicologists, environmental ecologists, and food scientists.♦ Silver speciation is of paramount importance when discussing both the benefits and the toxicities of silver preparations. In most every case, the benefits are determined by (a) the silver speciation content of oligodynamic silver ions, yet the toxicity of silver relates to (b) the <u>non</u>-oligodynamic silver content *plus* (c) the specific anion attached.

Furthermore, it is crucial to differentiate silver speciations even as they pertain to the category of colloidal silver preparations. As a nutraceutical, there is a high margin of safety when manufacturing a silver preparation that is only comprised of oligodynamic silver in ultra-pure water, a specific speciation of silver as a hydrosol.

MONOGRAPH SOURCES - There are in existence many speciations of silver products that have been listed in Official and Unofficial Pharmacopoeial Monographs. Generally these fall under two distinct speciation categories listed in drug compendiums, including:

- The Dispensatory of The United States of America (U.S.D.),[85]
- The British Pharmacopoeia (B.P.),
- The United States Pharmacopoeia (U.S.P.),[86]
- The National Formulary (N.F.),[87] and

- The New and Non-Official Drug Registry (N.N.R.), and in
- Other compilations made by The Council on Pharmacy and Chemistry of the American Medical Association.[88]

For practical discussions, the beneficial biologically activities of these silver preparations all relate to their oligodynamic action of the silver cations, whether colloidal in speciation or not. Exceptions would include some silver halides (AgI and AgCl), oxides of silver, and silver sulfadiazine, which have added actions contributed by their respective anions.

PERSPECTIVES PERTAINING TO NUTRACEUTICAL INCLUSION - Lastly, it is important to understand that all essential minerals currently known that are also metals, have a beneficial daily value (DV) range established by the National Academy of Sciences (NAS), as well as a toxicity threshold level. The NAS may take 10 years or more to established a DV for minerals, as has been the case for selenium; chromium, vanadium, molybdenum, nickel and other trace metal minerals, and the NAS may not officially cite all of the adjunctive functions such minerals and metal minerals may perform biologically that are known to the peer-reviewed literature.♦ The NAS typically forms a consensus only after thousands of studies have been compiled and appraised through the scientific revision process.♦ Although drug investigations may take up to 10 years before FDA approval is realized, the scientific research that attains this approval - in some ways – does not match the threshold criteria the NAS utilizes to determine official recognition of health effects or DVs for certain nutrients.♦ As this document is being written, the FDA is just now re-visiting this issue to make the "health claim" filing for nutrients more user friendly and attainable.[89]♦

In conclusion, we may learn of a legitimate adjunctive nutritional benefit for a metal mineral long before it is officially recognized. This may be especially true if accrued documentation on the metal has been largely concerned with defining the toxicity of the metal, without addressing the speciation issues in context, or the biological benefits suspected or already known to exist which lie just beneath the toxicity threshold level. This is where a type of "proof context" becomes illegitimate and harmful to the consumer. For example, The Dispensatory of The United States of American in 1937 cited metallic Selenium as extremely toxic.[90] Presently there are many selenium salts and chelates in wide use as nutraceuticals, such as sodium selenite, selenium methionate, selenium asparatate, selenium ascorbate, etc... Various copper drugs in that era apply in this context as well, and the same text listed over 19 speciations of this now essential metal mineral.[91]♦

It is important to bear all these facts in mind when viewing this proprietary silver hydrosol as a present day nutraceutical. The often recited quote relating to all colloidal silver preparations (CSP), stemming from the 1960 edition of the US Dispensary that, "there is no justification for this (internal) use either theoretically or practically"[92] is now obsolete in light of the preponderance of scientifically credible evidence showing the wondrous internal activities of oligodynamic silver ions – and necessarily including

active silver hydrosols – now made possible by advances in modern technology.♦ As to how this may apply to nutraceuticals verses pharmaceuticals, only time will tell.

♦***This document is not for public use.*** It is intended strictly for non-public information requests by private industries wishing to evaluate highest quality oligodynamic silver speciations. Our products are fully labeled and compliant with all FDA and FTC regulations when sold or promoted to the general public. This information is not intended to be viewed as providing drug information or for making any disease claims for Natural-Immunogenics Corp. or any of its nutritional supplements. These statements have not been evaluated by the FDA. This information is not intended to diagnose, treat, cure or prevent any disease.

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