The Safe and Non-Toxic Nature of American Biotech Labs® SilverSol Technology® Products (A Review Article)

By
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Abstract

American Biotech Labs® (ABL) SilverSol Technology® is a newly patented (#7135195) technology that is EPA approved and FDA approved. It is produced and sold as a liquid or gel. Hundreds of scientific studies have been reported to document the benefits and safe use in animals and humans. The purpose of this article is to review scientific studies, which experimentally test the safety of SilverSol. Results of this scientific review demonstrate the safety of American Biotech Labs SilverSol Technology® and identify it as a unique entity proven to be safe.

Results from safety and toxicology studies demonstrate credible and unanimous safety evidence from experimental testing performed in humans, animals, laboratories, hospitals, medical clinics, in vitro, injected, ingested, cytotoxicity and overdosed sources. Results from all these studies report safe, beneficial and non-toxic data.

The only adverse event known, from the medicinal use of silver, is Argyria. EPA reports have determined that administering one gram total elemental silver over a 2 year period presents no risk for developing Argyria (US EPA Silver; CASRN 7440-22-4 1996). According to a report from the EPA Re-registration Eligibility Document (RED), "the Office of Water classified silver as a Group D carcinogen (one that is not classifiable as to carcinogenicity in humans) in 1988" (12). The EPA established an oral Reference Dose (RfD), or daily intake limit, of 0.005 mg/kg/day for Silver in 1991 (12). This equates to an equivalent safe daily dose of 1 oz of 10 ppm silver sol.

The conclusion of this review is that American Biotech Labs (ABL) SilverSol Technology® is safe and non-toxic to healthy human cells, humans, animals, and meets safe USP, FDA, EPA and US Patent office standards.

Introduction

The newly patented ABL SilverSol Technology® is already approved and regulated by the EPA (disinfectant), where it currently carries a number of EPA approvals. ABL's SilverSol products are approved for and are currently in compliance with the following EPA registration #73499-2.

*22 ppm and 0.5 ppm for dental water line disinfection (diluted from 32 ppm).

*10 ppm as a hard surface disinfectant to kill gram negative organisms in industrial commercial and residential usage.

*32 ppm as a hard surface hospital disinfectant for gram positive, gram negative and nosicomial pathogens.

*Approved at 32 ppm to kill yeast and environmental fungi including black mold.

*Also approved for the disinfection of heating and ventilation systems, and for the killing of odor causing bacteria.

The United States Patent Office has approved a patent of SilverSol (American Biotech Labs Technology® US Patent # 7135195). SilverSol fulfills the definition of being non-toxic, in that it passes through the body unchanged, this means it does not produce any harmful metabolites. Marino (Chem. Bioil. Interactions, 1974), and Berger (Antimicrobial Agents, 1976), confirmed that the effective dosage level of pure silver sol is safe for mammalian tissues. The CRC Handbook to Chemistry and Physics (sec 15 pg 8) states:" While silver is not considered to be toxic, most of its salts are poisonous." This is why SilverSol containing only elemental silver and water is virtually devoid of toxicity. The only adverse event known, from the medicinal use of silver, is Argyria. EPA reports have determined that administering one gram total elemental silver over a 2 year period presents no risk for developing Argyria (US EPA Silver; CASRN 7440-22-4 1996). According to a report from the EPA Re-registration Eligibility Document (RED), "the Office of Water classified silver as a Group D carcinogen (one that is not classifiable as to carcinogenicity in humans) in 1988" (12). The EPA established an oral Reference Dose (RfD), or daily intake limit, of 0.005 mg/kg/day for Silver in 1991 (12). This equates to an equivalent safe daily dose of 1 oz of 10 ppm silver sol.

Nano Particles

The definition of a nano particle is that it must be a tiny .05 nano meters in size This means that only the smallest of particles can be placed under the label of nano particle. Some media groups suggest that a nano particle of a specific size (.001 nm) can be dangerous by collecting and sticking in the lungs causing cancer in a similar way that asbestos causes mesothelioma. Using Electron Microscopy, ABL's SilverSol Technology® is measured to be 20-30 nm and does not fit in the alleged size parameter. In addition ABL's SilverSol has the unique ability to separate into mobile 5-7 nm sub-particles allowing the particle to morph into or out of any situation (Roy, R. Material Science Investigation, 2008). The electron microscopy photos published in this study, illustrate the segmentation of ABL's unique SilverSol Technology® and its ability to utilize segmentation to adapt to its environment. For this and other reasons SilverSol Technology® is not going to be a threat to stick in the lungs.

In a publication on H5N1 Bird flu (Pedersen, 2008) ABL's SilverSol Products were used to help prevent the bird flu and a simultaneous toxicity study was performed wherein 10 times normal, 100 times normal, and 200 times normal amounts of ABL'S SilverSol were given to mice. Lung necropsy was performed to determine if the lung tissues were damaged. It was found that the lung tissues had reduced viral titers, were less inflamed and weighed less indicating that the lungs were not being harmed by nano particles. In addition the lower lung weights indicate that there was a reduction in the inflammation supporting the safety of the ABL's patented SilverSol as a safe particle.

The data surrounding ABL's SilverSol Technology® illustrates its uniqueness, and proves that it is a different and separate chemical entity from other silver and silver salt products. This is confirmed by the fact that the patent office approved a number of new patents on ABL's SilverSol Technology®. The FDA has approved a 510K registration which gives evidence supporting the safety and efficacy of ABL's SilverSol Technology® for wound care.

Review of Safety and Toxicology Studies

Human Studies

AIDS Toxicology (Pedersen, G., Hegde, D., The Journal of the Society of Healing Outcomes, 2007).

Immune compromised, human AIDS subjects were orally treated with ABL's liquid SilverSol (2 oz per day for 4 months). Results demonstrate safe and beneficial use as determined by a normalization of T-lymphocyte counts and a restoration back to normal or near-normal body weights. This demonstrates that ABL's SilverSol dosed 6 times normal are well tolerated and even beneficial to immune compromised human subjects when taken daily for four months (2).

Cytotoxicity Studies

SilverSol Gel Cytotoxicity Is Negative In 32 ppm Gel. Nelson Laboratories. Cytotoxicity Test of ABL's SilverSol gel (32 ppm). 2008.

Healthy mouse Heteroploid connective tissue cells were incubated with ABL's SilverSol gel to determine if the silver sol would damage, destroy or have a toxic effect on the healthy cells. Results indicate that there was no sign of toxicity and no damage to the healthy cells. This strongly suggests that ABL's SilverSol gel (32 ppm) is safe and non-toxic for healthy normal cells. (9).

Silver Sol 10 ppm And 22 ppm Were Not Cytotoxic To Healthy Cells. Viridis Biopharma. Virucidal Activity of ABL's ASAP Against Hepatitis B Virus and Cytotoxicity of ASAP, June 2003.

Silver Sol 10 ppm and 22 ppm liquids were tested against Hepatitis B virus and a concurrent cytotoxicity experiment was performed to determine if silver sol would destroy healthy cells while fighting a serious virus. Results indicate that ABL's SilverSol does not destroy healthy cells and is not toxic to the healthy cells tested (10).

Animal Studies

Injected Mouse Toxicity Study (Bhagwat, A.M., Shri, C.B., Patel Research Centre for Chemistry and Biological Sciences Mumbai, India.)

Test mice were given a single injection of 32 ppm ABL's SilverSol® (50ml/kg) and observations for 72 hours were taken. Vital organs were harvested and sent for histopahology where they were tested for abnormalities. All animals survived the 72 hour time period after injection and demonstrated normal feeding, grooming, and drinking behaviors and were observed to have no abnormalities (1).

Oral Ingestion of High Doses of SilverSol® Demonstrates No Toxicity In Rats. Nichols, J., Acute Oral Toxicity Study in the Rat, NAMSA, 2009.

ABL's Liquid SilverSol (22ppm) was orally administered to rats in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500. A single dose of 5 g/kg of body weight was orally gavaged into rats and observed for any sign of toxicity for the next 14 days. Results demonstrate that there was no mortality or significant evidence of toxicity observed in the rats, even in high doses (200 times normal dose). This data suggests that a dose of 5 g/kg of body weight would not be considered to be toxic when administered orally in rats. (3).

H1N1 Bird Flu Toxicity Controls Survive Mega Doses Of Silver Sol. (Pedersen, G.P., 2007 Journal of the society of Healing Outcomes, 2006).

Mice were orally administered ABL's SilverSol liquid twice a day for seven days, after which they were infected with a fatal dose of Bird Flu (H5N1) (2). There was a 100% increase in the ability to survive a bird flu infection. In addition there was a toxicology control group, which was given 10 times the normal dose, 100 times and 200 times the normal dose for 28 continuous days. Results indicate that all toxicology control mice survived and thrived as indicated by healthy feeding, and grooming followed by normal histopathology. This demonstrates the safety of Silver Sol even when taken orally (by mice) at levels two hundred times the normal dose (2).

Silver Sol (ASAP-AGX-32® Does Not Produce Delayed Skin Hypersensitivity In Guinea Pig Skin. Nelson Laboratories. Guinea Pig Skin Sensitivity. 2004.

ABL's SilverSol was administered to the guinea pigs by injection (ID). Seven days later a repeated injection was administered to determine if the skin had become sensitive or hyper sensitive to the silver. Topical administration of the silver was then applied to determine if delayed type hypersensitivity had developed. Fourteen days later the animals were re-challenged and found to have no sensitivity, or delayed type sensitivity as compared to the controls. According to the criteria for the test, the sensitization potential of the test product for the animals used in the study were classified as Grade 1 (no different than control, (11).

Silver Nanosolution Shows No Statistically Significant Toxicity In Rats. Hegde, B.M. Kasturba Medical College, Manipal University. A Pilot Study To Evaluate The Toxicity Profile Of Escalating Doses of ABL's Silver Nanosolution In Rats.

Rats were administered three different doses (0.5 ml, 1.0 ml, and 1.5 ml) once a day for 28 days to determine possibilities of toxicity in rats. The animals were tested for haematocrit, haemoglobin concentration, erythrocyte count, total differential leukocyte count, platelet count, blood clotting time, sodium, potassium, urea, creatinine, total protein and albumin, alanineaminotransferase, and aspartate aminotransferase. In addition all animals were subjected to histopahologic examination of the brain, lungs, liver, and kidneys. Results

showed that there was no statistically significant differences in body weight, changes in food consumption, haematological examinations and serum chemistry as compared to the control group animals. In addition no drug related clinical signs of death occurred and at necropsy the organ weights were comparable to the control group and demonstrated no histopathological changes. This means ABL's SilverSol is safe in high doses when administered orally in mice (8).

Laboratory Studies

Silver Sol Gel (32ppm) Produced No Mortality Or Toxicity In Mice. Bhagwat, A.M., To Determine The Acute Toxicity Of Silgel Administered Through Oral Route In Mice. Mumbai, 2009.

Mice were administered ABL's SilverSol Gel orally at doses of 50/mg/kg, 500 mg/kg, and 5000 mg/kg to determine acute toxicity. Results demonstrate that silver Sol gel produced no toxicity even at the highest dose of 5000 mg/kg when orally administered to mice (4). According to the Acute Toxic Class Method of Schedule (1992, 1995), ABL's SilverSol gel can be assigned to the unclassified category of safe use (4).

Silver Sol Does Not Destroy Probiotics. Leavitt, R.W., Brigham Young University, 2004. Selective Antimicrobial Activity of ABL's ASAP-AGX-32® Silver Solution Against Probiotics.

Silver Sol (up to 16 ppm liquid) was tested in combination with probiotics such as bifidobacteria, and found to not affect the good bacteria. It was discovered that ABL's SilverSol does not harm the anaerobic bifidobacteria (6).

Silver Sol liquid (10ppm and 22ppm) Causes No Negative Effects On Probiotic Bacteria. Viridis Biopharma. Selective Inaction Of ABL's ASAP (10ppm and 22ppm) on Probiotics. 2004.

Silver Sol 10ppm and 22ppm "have not demonstrated anti-pro-biotic activity…It indeed compliments therapy by sparing essential host micrflora as well as concomitant oral lactobacilli therapy normally given as an adjuvant" (7).

Governmental Approvals

The United States Patent Office has approved the patent for ABL's SilverSol Technology® Including numerous claims (United States Patent # 7135195).

The Environmental Protection Agency (**EPA # 73499-2)** has granted certification to ABL's SilverSol in the following classes:

- Industrial, commercial and residential
- Pesticide
- Surface disinfection
- Hospital disinfection

ABL's SilverSol has a hazardous spill Rating of 12,500,000 gallons.

The Food and Drug Administration **(FDA)** has approved silver sol gel as a device for wound care.

The Merck Manual of Diagnosis and Therapy, 1999.
Silver is not mentioned in Section 226 / Toxic Nephropathy, of the Merck Manual. (5). This indicates that Silver is not considered to be a heavy metal and it does not accumulate in the brain.

Conclusions

From the review of these scientific studies it is concluded that:
Silver Sol is a new technology that is patent approved, EPA approved (surface disinfectant) and FDA approved as a gel (Wound Care).

Silver Sol is safe in humans (AIDS Study).
Silver Sol is Safe in animals (Bird Flu Study).
Silver Sol is safe to healthy human cells (Cytotoxicity Study).
Silver Sol is approved by the FDA as a device for wound care (510K).
Silver Sol is safe in animals at 10 times, 100 times and 200 times the normal dose (H5N1 Study).
Silver Sol was safe in long-term use (28 Days).
Silver Sol was safe in a long term human HIV study (4 Months).

Silver Sol is safe in humans, animals and is non-toxic to healthy human cells.

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