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June 5, 2014
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U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Rockville, MD 20857
Dear Reviewers,

This information supports the petition to ban the addition of industrial synthetic fluoride compounds, sodium fluoride, fluorosilicic acid, and sodium fluorosilicate, into U.S. public drinking water supplies as an oral ingestible added for the purpose of whole body fluoridation to treat dental caries (petition #FDA2007-P-0346). Of course no request is made to remove natural calcium fluoride from public water supplies at levels below the EPA MCL/SMCL of 2-4 ppm. Unfortunately, the EPA and the CDC are unable to understand the vastly higher toxicity of industrial fluorides in calcium deficient water, and have produced no MCL for it. Also these agencies fail to distinguish between total contaminant final levels in water (from endogenous contamination plus that added) compared to the amount added directly from within the fluoridation materials themselves that are usually low enough to not exceed EPA MCL's after dilution during time of formulation.

Attached please find the recent article detailing metal contaminants present in fluoridation materials intended for human ingestion and sold for health purposes in the U.S. (Mullenix, P. *A New Perspective on Metals and other Contaminants in Fluoridation Chemicals,* **International Journal of Occupational and Environmental Health** 20(2):157, 2014). Although it is illegal *to intentionally* add these contaminants into public water or food (being EPA recognized contaminants and certainly food/beverage contaminants), the EPA does not halt the use of this material intended for ingestion. This is because after formulation and dilution by water districts as the delivering facility, the incremental increase in the contaminants above those already present in the water, in the absence of accidents, is lower than the EPA MCL. Fluosilicic acid materials directly add lead into the water reported by Mullenix typically in the range 0.6 to 1.1 ppb.

This demonstrates that current EPA administrators are not capable of properly regulating 'water fluoridation' intended for health purposes. It is the *total* contaminant concentration that must not exceed the MCL in the final product being ingested. It is not simply the contaminant concentration directly added by a water district (that adds to that from other sources). Further, what is most important is the level that is present just prior to ingestion and the total daily dosage ingested, not the concentration at the facility where the fluoridation material is initially added before transport to consumers through municipal systems. The EPA attempts to authorize certification of these materials to the NSF, who merely stamps the materials as "safe" for human ingestion as long as the amount after dilution from the materials is below the MCL, without regard for the contaminants already present in the water supply to be treated. And without consideration of transport systems used after the final diluted formulation is prepared. This is improper formulation practice for drugs, supplements, and dietary ingredients.

As a specific example of a location at which the Mullenix article concludes fluoridation must be halted, consider Anchorage, Alaska. Water quality reports indicate that lead levels reach 26.5 ppb at certain times, nearly twice the allowed EPA MCL of 15 ppb due to known adverse health impacts from chronic lead consumption at this level. The EPA will not halt the treatments even though the EPA Public Health Goal for lead is zero and the FDA allowed daily intake for children is a mere 0.006 mg (see below). This amount is contained in a mere 0.23 liters of such contaminated water!

As pointed out by Mullenix in the article, it is necessary to halt all fluoridation infusions in such cities because the EPA MCL is already occasionally exceeded for unknown reasons. Lead and arsenic levels measured in fluosilicic acid both vary between batches. They are always present in this source material, but are never present in sodium fluoride used for fluoridation. Fluoridation in any city must be halted if the level in water causes that added to exceed the EPA MCL, or if the MCL is occasionally already exceeded, particularly since batches are not tested prior to formulation. *The FDA requires routine testing of contaminants in all drugs and ingestible ingredients in the U.S.*

In Anchorage, the infusions cause the lead level to be exceeded for a more extended time than would have been exceeded in the absence of fluoridation. This is the case, regardless of NSF certification that the amount added from the chemicals themselves is less than 10% of the recognized EPA MCL. Who cares if the hazardous waste adds lead that is less than 10% of the MCL when the lead is already higher than the MCL anyway? And if additional contaminant accumulates into the final product during transport within the city infrastructure prior to ingestion, the certification is meaningless. As seen below, silicic acid in the waste fluosilicic acid material after dilution substantially leaches lead to levels far in excess of the EPA MCL in homes (see previous FDA letter Oct. 6, 2012). And water districts do not routinely analyze product water at homes, but merely conduct occasional spot checks.

A recent news report stated that Dallas, Texas council members are considering halting its water fluoridation program that has been ongoing for 50 years (see summary). I examined Dallas water quality reports over a seven year period of time to observe any trends in fluoride and lead concentrations in public drinking water (see attached graph). Again, fluorosilicic acid contains lead contamination and also contains silicic acid that leaches lead from lead-based plumbing fixtures. In Tacoma, WA, lead water levels plummeted after fluorosilicic acid infusions were halted, and raised again when the infusions returned (previous FDA letter Oct 6, 2012). The data from Dallas also confirm this phenomenon. It is most fortunate that Dallas chemists currently do not infuse the amount of fluoride that is requested by city officials. Note that the lead levels found are consistent with that expected from fluosilicic acid treatment (1 ppb reported in the Mullenix study for water at the treatment facility). This suggests that even now direct lead addition from the fluosilicic acid materials, at half the requested fluoridation level, is 36% (0.5 ppb/1.4 ppb) of the total lead present in Dallas water supplies. The remaining amount may be due to leaching or endogenous levels in water already present from other unknown sources.

Fluoride ingestion does not decrease dental caries and instead accumulates into bone and other tissues, causing bone weakening, effects on brain, increased morbidity when used in kidney dialysis wards, increased incidence of permanent abnormal teeth fluorosis with enamel hypoplasia, among other adverse effects [1-5]. The internal ingestion of fluoride compounds is not approved by the U.S. FDA [2]. *Fluoride infusions into water supplies to be consumed by the general public violate FDA regulations designed to protect consumers from unnecessary drug exposures.*

Historical water quality reports from Tacoma, WA indicated that lead levels in water parallel the amount of industrial fluorosilicic acid infused into the supply. The previous FDA letter (Oct. 6, 2012) described the lead levels that exceed the EPA MCL here in Carlsbad, CA homes even though the water supply lead level leaving the district treatment plant was below the MCL. This phenomenon is widespread across the U.S. and has been reported repeatedly in public news accounts in Washington, D.C., Chicago, IL, and Tacoma and Seattle, WA and, as above, Anchorage, AK. That letter also provided the explanation why fluosilicic acid with its orthosilicic acid product leaches lead from lead-based plumbing that sodium fluoridated water does not (see attached manuscript). At 0.7 ppm (0.04 mM) fluoride added, and lead at a positive 2 charge, the silicic acid in long-standing city water to complete reaction could theoretically produce up to 3 ppm lead (3,000ppb) if sufficient lead salts were present in that standing water. Indeed, levels as high as 1,600 ppb have been reported sadly in silicofluoridated Tacoma, WA schools. In Washington, D.C. total lead levels in summertime, where this reaction is more favorable than in winter, have exceeded 180 ppb, depending on the year. Although total variation in lead levels has not yet been explained, it is clear that lead levels in children have exceeded 10 ppb as a result of municipal water consumption in D.C. (Edwards, M., et.al. *Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001−2004,* **Environ. Sci. Technol**., 2009, 43 (5), pp 1618–1623). As our Nation's capital, this is an embarrassment.

. The EPA is unable to handle this widespread problem and is far too influenced by the CDC that promotes fluoridation practices. Chemist Susan Kanen from the University of Maryland worked at the Washington Aqueduct and participated in the lead water measurements in Washington, D.C. product water. She worked with the Army Corps of Engineers and provided the attached information. Notable is the summertime increased lead levels over wintertime (see graph). The EPA requested phosphate infusions, in hopes of mitigating this lead problem Oct. 2005, rather than halting the infusion of lead and silicic acid-containing fluosilicic acid, but this was ineffective in removing lead. The phosphate merely caused the free lead ion to be converted to a complex particulate that remained in the product water. The total lead in the drinking water remained the same (see the EPA reference at: http://www.epa.gov/dclead/TEWG030212.pdf).

As noted in the graph for Washington, D.C., the downward trend over years of time indicate that it is not the phosphate treatments, but that available lead over long time periods of years in the city water conduction system became more depleted. This of course does not deal with the problem but merely allows it to bleed out. The EPA assumed that the problem had been sufficiently mitigated with phosphate to avoid further action, because ionized lead was lowered, but the mitigation failed. Most important, lead phosphate is fully ionized in the acidic stomach at pH 3 anyway, where it is assimilated.

Since current EPA administrators will not ban the infusions, the EPA as currently staffed is unable to solve this problem. Only the FDA has the capability and authority to regulate and monitor total lead intake from various sources in U.S. children and to ban lead exposures that are unnecessary. Lead is a neurotoxic heavy metal that irreversibly binds protein sulfhydryls and can be particularly injurious to developing brain. Childrens' brains develop through age 20. The FDA established daily total intake of lead for children from foods and beverages and all other sources is limited to a PTTIL of 0.006 mg (6 micrograms) daily (see

http://www.fda.gov/food/foodborneillnesscontaminants/metals/ucm172050.htm).

> "This guidance rescinds the 0.5 ppm lead guideline for considering enforcement action because that level is no longer regarded as consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained."

Notice that an honorable mission of the FDA is to prevent lead exposure in any possible and practical way. Thus fluosilicic acid water fluoridation, with its lead and lead-leaching silicic acid, contradicts FDA goals because it always contains some lead AND all cities have some lead-plumbed neighborhoods.

Water fluoridation alone accounts for daily intakes in excess of this FDA limit because 1-2 liters of water can be consumed directly, which adds to that from foods made with municipal water including soups and stews, plus beverages made with municipal water. One liter of 15 ppb lead from water alone is 2.5 times the FDA PTTIL for total daily lead intake in children.

Further, FDA guidelines state that any entity that distributes and formulates materials intended as supplements for ingestion in U.S. consumers must measure contaminants in the FINISHED product consumed. No one in any municipality actually drinks water directly leaving a filtration plant where water quality reports make public the known contaminant levels. Drinking water is transported through city water systems to homes or businesses prior to ingestion. The www.FDA.gov site says at:

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm238182.htm

> "**Does the DS CGMP rule require any verification that a finished batch of dietary supplement meets product specifications?** Yes. The DS CGMP rule requires you to verify that a subset of finished dietary supplement batches (which you identify through a sound statistical sampling plan) meets product specifications (i.e., specifications that the DS CGMP rule requires you to establish under 21 CFR 111.70(e))."

Furthermore, the CFR regulations stipulate:

> **"What steps should I take if I use a municipal water supply?** If you use a municipal water supply, you should take steps to ensure that you are at all times aware of problems, such as an acute problem with microbial contamination or a long-term problem associated with lead pipes present in some parts of the city water supply, that may not be reflected in the municipal water report. (72 FR 34752 at 34821)."

If the CDER still intends to not ban fluosilicic acid infusions for the country, then please let us know the proper department to also contact within the agency. We need to honor the stated FDA mission to minimize lead exposure in U.S. children to a bare possible practical minimum. We prefer in fact that CDER work together with such a department to ban the sale of lead-containing, silicic acid producing fluosilicic acid intended to be ingested by U.S. consumers.

Also if the FDA cannot ban all industrial fluoride source materials from human intentional ingestion then could you at least consider a ban on fluosilicic acid and sodium fluosilicate since these contain lead and arsenic that sodium fluoride does not?

Additional comments:

Everyone in pharmacy and medicine knows that it is unethical to administer a drug or treatment chemical to anyone by infusing it into drinking water at a fixed single concentration in the water, to be ingested *ad libitum* by all peoples, sick, young, old, etc. This is partly because no two people drink exactly the same amount of water per body weight on any given day, so no one receives a particular single targeted dosage.

But few understand the additional more significant details of this story. That is, no two people are alike in their response to a drug even when a particular prescribed dosage is achieved. Even if a fixed daily dosage was achieved that produced precisely the same blood concentration in all consumers, this method of drug delivery without a prescription remains unethical. Why? Because no two people are exactly alike and no two people have the exact same response and sensitivity to a particular drug level in the blood. Some are allergic, some are hypersensitive, some have illness and are more or less dramatically perturbed than those who are well.

In the specific case for fluoride taken internally, some people lack normal kidney function, some have diabetes, some have Alzheimer's disease, low blood calcium, some have no dental caries their entire lives and don't need such a drug, some have lead or other heavy metal overexposure(s) already, some have stomach ulcers, anemia, and various bone disorders,. Therefore, for any desired dosage, some are affected as expected, some are not affected in a noticeable way, others are overly affected, and some are acutely observably harmed (see original FDA petition and previous letters).

It is improper for the U.S. Food and Drug Administration to allow whole body "fluoridation" of U.S. consumers by allowing an adjusted CONCENTRATION of fluoride in their drinking water. Regardless of extent of harm or argued level of effectiveness, *this fact alone compels the FDA to ban the sale of all industrial fluoride compounds intended to be ingested in the United States by formulating drinking water with a a particular concentration* of the chemical with the intention to whole body fluoride treat ALL humans in the U.S. population.

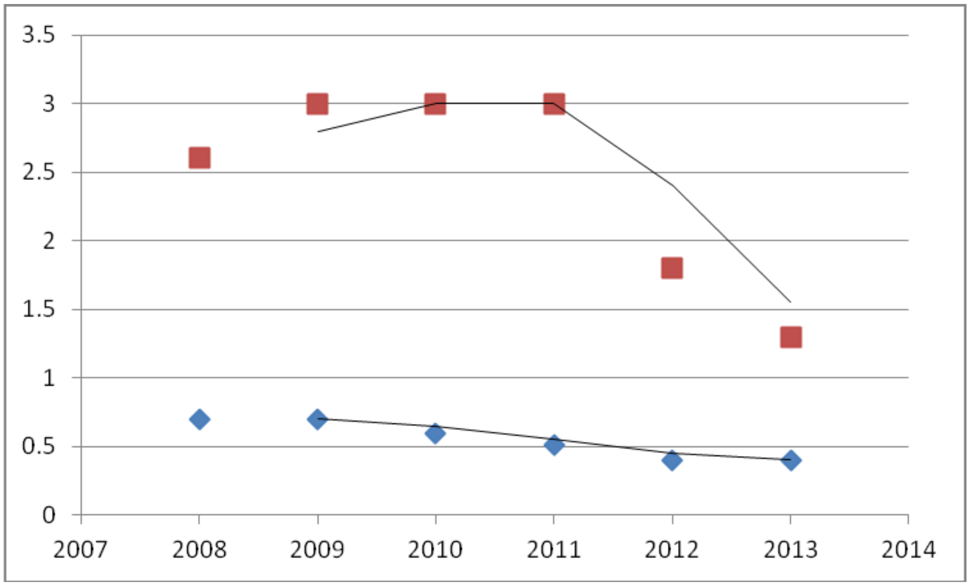
Thank you, Richard Sauerheber, Ph.D. Chemistry

References

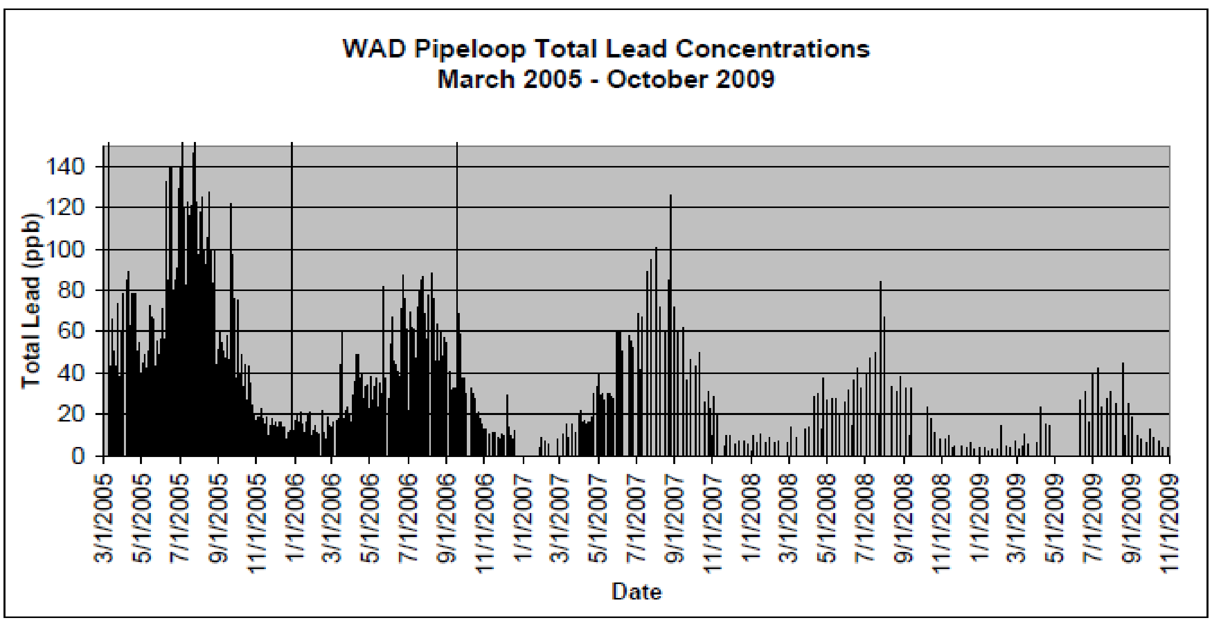
1. Peckham, S. and Anwofeso, **The World Scientific Journal**, March, 2014.
2. Sauerheber, R., **Journal of Environmental and Public Health**, 2013 #439490.
3. National Research Council, **Report on Fluoride in Drinking Water**, 2006.
4. Connett, P., Beck, and Micklem, **The Case Against Fluoride** (2010).
5. Sutton, P. **Fluoridation: Errors in Omission and Commission**, 1986.

Supportive materials: a. Dallas city council member statements
b.Dallas water lead contamination and fluoride level graph
c.Mullenix article abstract
d.EPA report of trends in total lead levels in Washington, D.C. fluoridated water.

Dallas, Texas drinking water fluoride and lead content as a function of year



Dallas, Texas water quality report public data are plotted for fluoride (ppm) (lower diamonds) and lead (ppb) (upper squares) as a function of year. Industrial fluorosilicic acid infusions for its fluoride content are responsible for the total fluoride present. Total fluoride infusions into water have been steadily decreasing since 2011 to the current average level of 0.4 ppm (range 0.32 -.44) in 2013. The corresponding lead concentration has proportionately decreased from approximately 3 ppb to the current level of 1.3 ppb. This appears to be due to known lead contamination present in fluorosilicic acid waste produced during fertilizer manufacturing sold to the city as an oral ingestible fluoride material. Data are from Dallas water quality reports available at: http://www.dallascityhall.com/dwu/water_quality_reports.html.



Data were forwarded from Susan Kanen working with the Army Corps of Engineers for the EPA on lead levels in silicofluoridated Washington, D.C. water supplied to homes. The summer increases in lead concentrations far exceed the EPA MCL, by 10 fold. Since lead levels at water treatment plants are far lower, the EPA will not halt the infusions. Additional data forwarded by Kanen is described in the following link at the EPA, where total lead and ionized lead levels were measured in the silicofluoridated Chicago water supply as a function of time before and after phosphate infusions were undertaken. Kanen is now a member of **Fluoride Free Alaska** and kindly provided this link proving that the EPA has no remedy with phosphates for cities with lead levels that exceed the MCL (see http://www.epa.gov/dclead/TEWG030212.pdf).

How Does Fluorosilicic Acid Leach Lead?
And Why Does Fluorosilicic Acid Leach Lead So Much More Than Sodium Fluoride Does?
Richard Sauerheber, Ph.D.
With contributions from James Robert Deal J.D.

Background: There is virtually no lead in Everett's pristine water source, Spada Lake, just north of Sultan, in the heart of the "convergence zone", where the winds which went north to get around Mount Olympus converge with the winds which went south to get around Mount Olympus, and which gets 140 inches of rainfall each year. In 1991 Everett's city fathers were scammed into "fluoridating" Everett's water, not knowing at the time that the so-called fluoride, commonly known as fluorosilicic acid, H_2SiF_6, contained small amounts of a score of poisonous elements and compounds, including lead. The fluorosilicic acid used to fluoridate can bring with it and add up to 1.1 ppb lead to drinking water, according to the National Sanitation Foundation.

As bad as 1.1 ppb lead is, there is enormously more lead at the tap. How can this be? This is so because there is lead in old service lines, old galvanized pipe, copper solder, and water taps, and fluorosilicic acid – and its break down compound orthosilicic acid – leach lead very well.

We hear a lot about paint as a source of lead poisoning, but almost nothing about lead in drinking water. It is a health district blind spot. This is not a trifling matter. Lead has been measured at up to 63 ppb at random taps in Everett and up to 1,600 ppb in Seattle school drinking fountains.

Coplan, Masters, Maas, and Sawan showed that that there is much more lead in tap water fluoridated with fluorosilicic acid than with sodium fluoride. However, they did not explain the mechanism by which fluorosilicic acid dissolves lead.

Industrial grade fluorosilicic acid components are the most widely consumed non-nutritive chemical substance in the world. Because fluorosilicic acid is much cheaper than sodium fluoride, it is used in 90% of water districts which fluoridate.

When diluted in water, fluorosilicic acid breaks down into fluoride ion, hydrogen fluoride, and orthosilicic acid, H_4SiO_4, as the 2006 NRC study on fluoride stated. Little has been written in the fluoridation debate about orthosilicic acid, and that has been a mistake. Orthosilicic acid is classed as a weak acid and is often dismissed as relatively harmless. Unfortunately for our health, it is able to dissolve – slowly but surely – lead salts out of lead based pipes and fittings, especially brass.

In Tacoma, WA when silicofluoridation was halted for district repairs, the lead level in the provided public water plummeted. After the infusions were reinstituted, the high lead levels returned. Recent data demonstrate that in the city of Dallas, Texas lead levels in public water supplies follow the concentration of added industrial fluoride. In 2011 Dallas lowered the fluoride concentration in response to requests from HHS to lower fluoride levels to under 0.7 ppm. The fluoride level was reduced from 0.7 to 0.4 ppm as a precaution..The lead level correspondingly plummeted from 3 ppb to 1.6 ppb, as expected (see Figure).

The mass treatment of public fresh drinking water with industrial fluorosilicic acid to produce fluoride ion at 1.0 ppm also produces approximately 6 ppm sodium ion and .7 ppm orthosilicic acid. None of these belong in fresh drinking water. And neither fluoride no silicic acid are normal components of the human or animal bloodstream.

Unique Chemical Properties of Orthosilicic Acid.

It is essential to understand selected unusual chemical properties of orthosilicic acid. The first dissociation constant of this acid in water is very low, 2×10^{-10}, and it is therefore classified as a 'very weak' acid.

Aside: The dissociation constant is the ratio of the concentration of hydrogen ion protons times the silicate anion concentration divided by the concentration of the intact acid at a given temperature. Strong acids dissociate completely in water, and their dissociation constants are high as not to be accurately measurable. Strong acids with pH less than zero may be used for destructive purposes such as rapid oxidation and dissolution of metals that weak acids do much less readily or cannot do at all.

However, the terms strong and weak applied to acids are relative. In the stomach hydrochloric acid is a strong acid, which at dilute concentrations and a pH of 3, assists with digestion of food. The gastric mucosa lining of the stomach protects the rest of the body from this acidic environment. The intestines then neutralize HCL with weak base bicarbonate and a wide variety of 'weak' acid/base conjugate pairs in sufficient amounts so that body extracellular fluids are maintained at a pH of 7.4. The pH of the bloodstream is the most tightly regulated parameter in all physiology, and deviations of only ± 0.2 pH units causes unconsciousness. Through autonomic neural brain pathways, breathing rates are automatically adjusted to retain proper pH by adjustment of carbon dioxide through exhalation and carbonic acid/bicarbonate ratios in the blood.

Note that strong acids are rendered neutral by the addition of either equal amounts of strong base or the addition of larger amounts of weak conjugate base such as bicarbonate or biphosphate, turning the acid into a harmless conjugate. Most important for this discussion, note that "weak" acids are nevertheless capable of important physiologic effects, that is by acting as acid catalysts or as reactants. Strong acids cause skin burns, but the weak acid hydrofluoric acid HF, one which does not dissociate well, causes even more serious burns and does deeper tissue damage. Because the HF molecule is neutral and very small, it can slip easily through the neutral fatty lipid layer and slowly penetrate deeply into the body. The point is that some weak acids can be extremely harmful.

Orthosilicic 'weak' acid has been long used in agriculture to break down solid calcium phosphate $Ca_3(PO4)_2$, thereby releasing soluble phosphate ion in soils even at neutral pH, for uptake by plant life. The reaction of silicic acid with calcium phosphate under neutral pH conditions is: $H_4SiO_4 + Ca_3(PO_4)_2 \rightarrow HPO_4^{-2} + 3Ca^{2+} + PO_4^{-3} + H_3SiO_4^-$. This reaction occurs at a pH where any strong acid would have been neutralized. This reaction is relevant not only to calcium phosphate in soil but also to calcium phosphate in teeth enamel. By means of orthosilicic acid, enamel is subject to slow and progressive degradation. This is so because the dissociation constant for biphosphate, HPO_4^{-2}, is only approximately 1 x 10^{-12}, which is much lower than that for silicic acid, which again is 2 x10^{-10}.

The pH of drinking waters in the U.S. typically range from 7 to 8.4 and remains so after treatment with fluorosilicic acid because the industrial acid is neutralized by the injection into water of alkalizing agents, usually caustic soda, NaOH, also known as Drano which is a strong base, or in the case of Everett and Seattle by sodium carbonate, Na_2CO_3, a weak base, also known as soda ash. While this neutralization works on fluorosilicic acid, it does not work on orthosilicic acid because of orthosilicic acid's low dissociation constant. The pH would have to be raised to roughly 10 before the alkalinizing agent would neutralize the orthosilicic acid, but it would be impractical or impossible to raise the pH to 10, because doing this would create a new set of problems. Thus, the intact orthosilicic acid is fully retained in all treated drinking water, ready to dissolve lead in service lines, copper pipe solder, and plumbing faucets when the water gets to the home.

After assimilation, orthosilicic acid remains intact throughout the body except that silicate is known to incorporate into bone calcium phosphate and into collagen. Orthosilicic acid is eliminated by healthy kidneys, but a substantial amount is retained in kidney and other tissues.

As with any acid, orthosilicic is also capable of reacting with any metal having a reduction potential greater than hydrogen. Lead and aluminum are such metals, having reduction potentials greater than that for hydrogen, -0.13 and -1.66 volts, respectively.

Moreover, orthosilicic acid will leach aluminum from cookware and can contribute to significant uptake of aluminum ion in fluoride treated water. Although the Alzheimer's Association no longer recognizes officially that aluminum may cause this disease, nevertheless aluminum is often found complexed to abnormal proteins in the brains of those afflicted with this disease. Even if aluminum is not a primary cause in some cases of Alzheimer's, it could certainly aggravate the condition and at minimum most certainly does not belong in brain tissue. For this reason alone, given the fact that Alzheimer's incidence is rising precipitously in the U.S., the infusion of industrially produced orthosilicic acid and fluoride intentionally into public water supplies should be considered a contraindication.

Silicic Acid Entry into Public Water Supplies.

Thus it happens that silicic acid, a primary breakdown chemical of fluorosilicic acid, makes its way into most fluoridated water. During neutralization of the acid with caustic soda, every 30 tons of fluoridation materials added produce about 10 tons of fluoride ion, 10 tons of sodium ion, and 10 tons of intact orthosilicic acid. When diluted the reaction is:

$H_2SiF_6 + 4NaOH \rightarrow 4F^- + H_4SiO_4 + 4\ Na^+ + 2HF$,

When fluoride ion is present at 0.8 ppm and water pH is 7.4, currently the situation in Everett and Seattle, there will be approximately 0.7 ppm free fluoride ion, around 0.6 ppm orthosilicic acid, and around 0.6 ppm sodium ion products. There will be trace amounts of hydrofluoric acid HF (and much more at stomach pH). Note that the principle of conservation of mass of course applies, where 1.9 mg of starting materials (the total mass of fluorosilicic and soda added) yield 1.8 mg of product materials per liter of water treated.

Turning to hydrofluoric acid, again at a water pH of 7.4, the HF level is only around 0.05 ppb (2 x 10-9 M); however, the intact orthosilicic acid concentration at 0.6 ppm (6 x 10^{-6} M) is over 3,000 times greater. Thus, orthosilicic acid is the chief weak acid generated in the process, rather than hydrofluoric acid. (The 0.05 ppb level of HF at pH 7.4 is calculated from the Henderson-Hasselbach equation, pH = pKa + log [F-]/[HF] where the pKa for HF dissociation is approximately 3.2. See Lide, editor, **CRC Handbook of Chemistry and Physics**, Chemical Rubber Company).

The fact that fluorosilicic acid infusions cause elevated blood lead in children living in homes with old lead-based plumbing has been confirmed in follow-up studies.

Lead ion in Drinking Water and Fluorosilicic Acid.

NSF admits that some lots of fluorosilicic acid produce after dilution up to 1.1 ppb lead in the product water. This level is after dilution 230,000 times to get the fluoride ion down to 1.0 ppm, and so this is the maximum part of total lead which comes from the fluoridation materials. Although below the EPA Maximum Contaminant Level of 10 ppb, 1.1 ppb lead is a significant amount of lead, but much more significant is the amount of lead leached from pipes by orthosilicic acid. Random taps in Everett have shown lead up to 63 ppb. Lead levels were measured at 1,600 ppb in Seattle school drinking fountains.

Coplan, Masters, Maas, and Sawan published that that there is much more lead in tap water fluoridated with fluorosilicic acid than with sodium fluoride, and that blood lead levels were higher. However, as stated previously, they did not explain the mechanism by which fluorosilicic acid dissolves lead and increases blood lead levels. Many ask how is it possible that fluorosilicic acid and sodium fluoride both yield the same amount of fluoride ion when dissolved in our drinking water, but fluorosilicic acid leaches so much more lead than does sodium fluoride.

The answer to this question is that it is not the fluoride which dissolves the lead well, but the orthosilicic acid (H_4SiO_4), the primary breakdown product left when fluorosilicic acid is diluted to the point where fluoride ion is at 1.0 ppm at neutral pH (see National Research Council, **Report on Fluoride in Drinking Water, 2006 p. 53**). This is the orthosilicic acid form that remains the intact acid even at a very alkaline pH of 10 because its dissociation constant K_a is only 2 x 10^{-10}. Thus it is the intact orthosilicic acid, the predominant acid form present over the pH range 7 to 10 that is leaching lead or lead salts from pipes and plumbing fixtures where the following reactions can occur:

$$2H_4SiO_4 + Pb(s) \rightarrow Pb^{2+} + H_2 + 2H_3SiO_4^-.$$

It is well known that even the weak organic acids including intact acetic acid (CH_3COOH) dissolve lead, despite the fact that the potent hydrofluoric acid, HF, is unable to dissolve lead well (see **Merck Index**, 9th edition, 1976, entry 5242, p. 5235). Orthosilicic acid is a 'weak' acid, remaining un-ionized at high pH, but this makes the acid able to react at alkaline pH with lead, or especially lead salts known to typically line old pipe surfaces such as lead hydroxide, lead phosphate or lead carbonate where, since the K_{a2} for bicarbonate is 2 x 10^{-11} the following reaction occurs:

$$2H_4SiO_4 + PbCO_3 \rightarrow 2HCO_3^- + Pb^{2+} + 2H_3SiO_4^-.$$

And the K_a for HOH is 10^{-14} where the following reaction occurs:

$$2H_4SiO_4 + Pb(OH)_2 \rightarrow Pb^{2+} + 2H_3SiO_4^- + 2OH^-.$$

Coplan and Masters found that brass fixtures containing lead are most susceptible to fluorosilicic acid treated water. They demonstrated that higher blood lead levels occur in children ingesting this treated water compared to water treated with either sodium fluoride or left untreated. It is not surprising that fluorosilicic acid treatment of water might cause increased lead levels in blood, while sodium fluoride treatment does not. Infusions of industrial fluorosilicic acid typically produce after dilution into municipal water supplies roughly equal amounts of fluoride ion, sodium ion and intact orthosilicic acid (NRC, 2006, p. 56). It is orthosilicic acid which is responsible for the increased lead leeching from plumbing.

The pH at which orthosilicic acid is neutralized (i.e. ionized) by caustic soda, so it would be unable to react with lead or its salts, is very high, above pH 10. Its pK_a of 9.7 is the pH at which the acid would only be half-dissociated. The higher the acid content, the more corrosive the orthosilicic acid can be.

Fluorosilicic acid treated water dissolves lead from pipes more readily than does sodium fluoride treated water, even though the HF trace concentration is the same at a given fluoride level from either source. Therefore, as expected, it may be the un-ionized orthosilicic acid that is responsible for the dissolved lead from pipes exposed to this acid in waters treated with fluorosilicic acid, but which is not present in water treated with sodium fluoride.

References

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Neurotoxicology. 2000 Dec;21(6):1091-100.**Association of silicofluoride treated water with elevated blood lead.**
Masters RD[1], Coplan MJ, Hone BT, Dykes JE.

Abstract Previous epidemiological studies have associated silicofluoride-treated community water with enhanced child blood lead parameters. Chronic, low-level dosage of silicofluoride (SiF) has never been adequately tested for health effects in humans. We report here on a statistical study of 151,225 venous blood lead (VBL) tests taken from children ages 0-6 inclusive, living in 105 communities of populations from 15,000 to 75,000. The tests are part of a sample collected by the New York State Department of Children's Health, mostly from 1994-1998. Community fluoridation status was determined from the CDC 1992 Fluoridation Census. Covariates were assigned to each community using the 1990 U.S. Census. Blood lead measures were divided into groups based on race and age. Logistic regressions were carried out for each race/age group, as well as above and below the median of 7 covariates to test the relationship between known risk factors for lead uptake, exposure to SiF-treated water, and VBL >10 microg/dL.

RESULTS: For every age/race group, there was a consistently significant association of SiF treated community water and elevated blood lead. Logistic regressions above and below the median value of seven covariates show an effect of silicofluoride on blood lead independent of those covariates. The highest likelihood of children having VBL> 10 microg/dL occurs when they are both exposed to SiF treated water and likely to be subject to another risk factor known to be associated with high blood lead (e.g., old housing). Results are consistent with prior analyses of surveys of children's blood lead in Massachusetts and NHANES III. These data contradict the null hypothesis that there is no difference between the toxic effects of SiF and sodium fluoride, pointing to the need for chemical studies and comprehensive animal testing of water treated with commercial grade silicofluorides.

PMID: 11233755 [PubMed - indexed for MEDLINE]

Silicofluorides and Higher Blood Lead

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June 17, 2001

At present, U.S. public water systems serving over 140 million people are fluoridated with 200,000 tons of commercial grade hydrofluosilicic acid (H_2SiF_6) and sodium silicofluoride (Na_2SiF_6), together called "silicofluorides" (or "SiFs"). Data from numerous studies show that, taking economic, social and racial factors into account, where silicofluorides are used, children absorb more lead from the environment, and there are higher rates of diseases and behavioral problems associated with lead poisoning (including hyperactivity, substance abuse, and violent crime).

Although some early studies showed differences between sodium fluoride and sodium silicofluoride, to this day the substitution of silicofluorides in public water treatment facilities has never been subjected to appropriate animal or human testing. Recently, the Assistant Administrator of the EPA admitted to Congress that his agency had no data on SiF toxicity and the Chief of the Treatment Technology Evaluation Branch at the National Risk Management Research Laboratory confirmed that the EPA has "no" data on the "health and behavioral effects of fluosilicic acid."

Despite claims of safety by oral health officials, laboratory research in Germany revealed that silicofluorides do not dissociate completely and have important biological effects. To follow up on this issue, we have compared children's blood lead levels in communities using SiF treated water with communities using sodium fluoride or with non-fluoridated water. In three separate samples, totalling over 400,000 children, SiF treated municipal water is ALWAYS significantly associated with increased blood lead levels in children.

This effect was evident in a Massachusetts survey of lead levels in 280,000 children (see graph for children exposed to SiF from the Greater Boston water system, from towns that add SiF locally, or from communities using sodium fluoride, and towns without fluoridation). For the state of New York, data was available on venous blood lead levels for 151,225 children in communities of 15,000 to 75,000. Controlling for other factors associated with higher blood lead, silicofluorides were again significantly associated with higher uptake of lead from the environment. For black children, who are especially at risk for high blood lead, those in towns using SiF were less likely to have low blood lead and more likely to have lead over 10µg/dL. To confirm that these results are not due to other socio-economic or demographic factors, additional statistical tests were run (see two graphs below).

The third study concerned children's blood lead levels in the National Health and Nutrition Evaluation Survey (NHANES III), which had reports for 7224 children from 80 counties with populations over 500,000. Since only 4 of these counties had any communities that used sodium fluoride, analysis of the NHANES III data focused on the percentage of the entire county population exposed to silicofluoride treated water.

Among the 1543 children of all ages from large urban counties with over 80% of the population exposed to fluoridation (almost all of whom receive water treated with SiF), average blood lead was 5.12 µg/dL whereas the average for 1139 children in low fluoride exposure counties was 3.64 µg/dL Blood lead in the 473 children sampled from the medium fluoridation counties was 3.23 µg/dL, which was significantly different from the high fluoridation counties but not from either low fluoridation counties or those with unknown fluoridation status, where average blood lead levels were 3.16 µg/dL (S.D. 2.83). Controlling for the Poverty, the effect of SiF use was highly significant ($p < .0001$). When the sample is divided by age and race, these findings provide six separate samples in which SiF is associated with high blood lead (see Graphs).

In all three populations studied, those children in each racial category and each age group who were highly likely to be exposed to silicofluorides differ strongly in levels of blood lead from those not exposed. This conclusion was further checked by analyzing available data for health and behavioral traits that have been associated with high blood lead (such as violent crimes, cocaine use and asthma). In each case, those exposed to silicofluoride treated water were more likely to have behavioral or health problems that are more likely among those with high lead in their bodies.

The injection of silicofluorides in public water supplies is a practice whose elimination could possibly contribute to reduced rates of learning disabilities, substance abuse, violent crime, and asthma (all connected with lead poisoning and other toxins). Whatever the benefits to teeth (and this is highly controversial), our research shows that the issues facing the public concern silicofluoride chemistry, toxicology, and the linkage of neurotoxins with behavior or health. Before SiF chemicals are used, citizens must know that they are safe for all.

For more information, see: http://www.dartmouth.edu/~rmasters/ahabs.htm. (Note: from this site, that one can download an English translation of Westendorf's studies of silicofluorides, which have not hitherto been available in the U.S.)

Confirmation of and explanations for elevated blood lead and other disorders in children exposed to water disinfection and fluoridation chemicals

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Abstract Silicofluorides (SiFs), fluosilicic acid (FSA) and sodium fluosilicate (NaFSA), are used to fluoridate over 90% of US fluoridated municipal water supplies. Living in communities with silicofluoride treated water (SiFW) is associated with two neurotoxic effects: (1) Prevalence of children with elevated blood lead (PbB > 10 mg/dL) is about double that in non-fluoridated communities (Risk Ratio 2,x2p<0.01). SiFW is associated with serious corrosion of lead-bearing brass plumbing, producing elevated water lead (PbW) at the faucet. New data refute the long-prevailing belief that PbW contributes little to children's blood lead (PbB), it is likely to contribute 50% or more. (2) SiFW has been shown to interfere with cholinergic function. Unlike the fully ionized state of fluoride (F-) in water treated with sodium fluoride (NaFW), the SiF anion, [SiF6]2- in SiFW releases F- in a complicated dissociation process. Small amounts of incompletely dissociated [SiF6]2- or low molecular weight (LMW) silicic acid (SA) oligomers may remain in SiFW. A German PhD study found that SiFW is a more powerful inhibitor of acetylcholinesterase (AChE) than NaFW. It is proposed here that SiFW induces protein mis-folding via a mechanism that would affect polypeptides in general, and explain dental fluorosis, a tooth enamel defect that is not merely ''cosmetic'' but a ''canary in the mine'' foretelling other adverse, albeit subtle, health and behavioral effects. Efforts to refute evidence of such effects are analyzed and rebutted. In 1999 and 2000, senior EPA personnel admitted they knew of no health effects studies of SiFs. In 2002 SiFs were nominated for NTP animal testing. In 2006 an NRC Fluoride Study Committee recommended such studies. It is not known at this writing whether any had begun.

Ch/L – nsnbc 25.04.2014 DallasFluoridationTexas

After months of regular visits by citizens to city council meetings, warning about the risk involved with water fluoridation. Dallas City Council member Sheffie Kadane discussed ending the the fluoridation with City Manager A.C. Gonzales.
Ardent anti-fluoridation advocates were surprised, when months of regular visits to City Council meetings had another result than usual, reported NBC5 Dallas Fort Worth. These council members mention this practice has been shown to be inefficient and to cause more harm than good. Dallas City Council Member Sheffie Kadane said he discussed ending fluoridation with City Manager A.C. Gonzalez, reported NBC5, citing Kadane as saying:

"We don't need it and we'd just save a million dollars that we can use for something else. ... We're looking into seeing what we can do immediately so we can get those funds up front now."

Kadane was backed by Council members Scott Griggs and Jennifer Staubach Gates. Anti-fluoridation activist Regina Imburgia said: *"Yeah. ... This is major big. I knew we would prevail. It only makes sense. We're spending too much money on an ineffective program".*

She added, that she is more concerned about the possible health impact of drinking fluoridated water and that toothpaste with fluoride is a better way to fight tooth decay. Comments by city officials, for their part, dealt with potential savings rather than health issues. Numerous studies have documented that fluoride reduces tooth decay if it is used topically, that is for example in fluoridated tooth paste. Studies have also shown that one does not achieve adequate results by metabolizing fluoride in the digestive system after ingesting it. To the contrary, latest research suggests that fluoride is linked to a number of neurological risk factors.

In an article, published in The Lancet, Philippe Grandjean MD from the Department of Environmental Health at the Harvard School of Public Health, and Philip Landrigan MD, from the Icahn School of Medicine at Mt Sinai, New York, state that industrial chemicals that injure the developing brain are among the known causes for the rise in prevalence. The study links the industrial chemical to the epidemic rise in neurodevelopmental disorders including ADHD, dyslexis and autism. Since 2006, epidemiological studies documented six newly recognized neurotoxicants, one of which is fluoride.

International Journal of Occupational and Environmental Health

Volume 20 Issue 2 (April–June 2014), pp. 157-166

A new perspective on metals and other contaminants in fluoridation chemicals

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Background: Fluoride additives contain metal contaminants that must be diluted to meet drinking water regulations. However, each raw additive batch supplied to water facilities does not come labeled with concentrations per contaminant. This omission distorts exposure profiles and the risks associated with accidents and routine use.

Objectives: This study provides an independent determination of the metal content of raw fluoride products.

Methods: Metal concentrations were analyzed in three hydrofluorosilicic acid (HFS) and four sodium fluoride (NaF) samples using inductively coupled plasma-atomic emission spectrometry. Arsenic levels were confirmed using graphite furnace atomic absorption analysis.

Results: Results show that metal content varies with batch, and all HFS samples contained arsenic (4·9–56·0 ppm) or arsenic in addition to lead (10·3 ppm). Two NaF samples contained barium (13·3–18·0 ppm) instead. All HFS (212–415 ppm) and NaF (3312–3630 ppm) additives contained a surprising amount of aluminum.

Conclusions: Such contaminant content creates a regulatory blind spot that jeopardizes any safe use of fluoride additives.

See: http://www.maneyonline.com/doi/abs/10.1179/2049396714Y.0000000062

Lead typically measured 10 ppm in fluosilicic acid fluoridation materials. After infusion to desired levels in the final product water the lead level ranged from 0.6 to 1.1 ppb.
Arsenic and lead were always present in silicic acid materials but not in sodium fluoride materials used for fluoridation.