



February 1, 2008

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Subject: ***Request for Investigation of Nursery Water – Potential False Advertising and Misleading Health Claims on Fluoride in Bottled Water That Is Marketed to Infants***

Dear Ms. Parnes and Dr. Ellwood:

We are writing to request your investigation of apparent false advertising and misleading health claims by Nursery Water, a bottled water company that markets water with added fluoride for use in infant formula.

Federal Trade Commission (FTC) enforcement policy clearly states that companies cannot skirt federal health claim regulations by selectively publishing health claims in advertising but not on product labels: “Food marketers should not expect to circumvent FDA’s petition process for health claims simply by limiting the assertion of unapproved or unreviewed claims to advertising.” (emphasis added) and that “The absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission’s assessment of the adequacy of substantiation for the claim” (FTC 1994).

Not only is Nursery Water making unapproved and unreviewed health claims in its advertising materials without notifying the FDA as required by federal law, but the company is also making a health claim that has been specifically excluded by the FDA, as detailed below (emphases added):

- Nursery Water’s health claim: ***“The added fluoride will help strengthen your little one’s teeth”*** and water fluoridation is endorsed ***“as the single most effective measure to prevent tooth decay”*** ([www.nurserywater.com/nursery/product.php](http://www.nurserywater.com/nursery/product.php) and [www.nurserywater.com/nursery/fluoride.php](http://www.nurserywater.com/nursery/fluoride.php)).

FDA’s position: Certain fluoride-containing bottled waters are eligible for the following claim language: “Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]” but ***“the health claim is not intended for use on bottled water products specifically marketed for use by infants”*** (FDA 2006).

The company then violates the spirit if not the letter of the regulations by publishing on its website a smorgasbord of misleading direct and implied claims asserting and implying that fluoride in water for infants is recommended by the Centers for Disease Control and Prevention (CDC), the American Dental Association (ADA), and the American Academy of Pediatrics (AAP). Our review of these organization's positions on fluoride shows that none of them supports the use of added fluoride in water during infancy, when risks for fluoride-induced tooth damage (fluorosis) and other potential health impacts are higher than at other times of life. These positions are detailed below, with emphases added.

- Nursery Water's advertising claim: "Made according to recommendations by the American Academy of Pediatrics (AAP)" ([www.nurserywater.com/infants/bfeed.php](http://www.nurserywater.com/infants/bfeed.php)).

American Academy of Pediatrics position: ***Supplementary fluoride should not be provided during the first 6 months of life*** (AAP 2005).

- Nursery Water's advertising claim: "Drinking distilled water with added fluoride in the proper amounts has been shown to be so effective that the ADA supports municipal water fluoridation and refers to this as the single most effective measure to prevent tooth decay. This has also been ***endorsed by the Center for Disease Control and Prevention***, labeling municipal water fluoridation as one of the greatest public health achievements of the 20<sup>th</sup> century" ([www.nurserywater.com/nursery/fluoride.php](http://www.nurserywater.com/nursery/fluoride.php)).

Centers for Disease Control and Prevention's position: "***...when infant formula concentrate is mixed with fluoridated water and used as the primary source of nutrition, it may introduce fluoride at levels above the amount recommended to minimize the risk for fluorosis***" (CDC 2007).

- Nursery Water's advertising claim: "Specially formulated to ***contain the ADA recommended level of added fluoride***, the steam distilled water ***helps to strengthen teeth***" ([www.nurserywater.com](http://www.nurserywater.com)).

American Dental Association's (ADA's) position: "[Fluoride] **Supplements are not recommended for children under six months of age....**[T]he ***occasional*** use of water containing optimal levels of fluoride should not appreciably increase a child's risk for fluorosis,"... but "ready-to-feed formula is preferred," since it typically contains no added fluoride, and concentrated or powdered formula "**can be mixed with water that is fluoride free**" or that contains little to no fluoride, such as water that is "purified, demineralized, deionized, distilled, or reverse osmosis filtered water." (ADA 2006).

It also appears that Nursery Water's bottled water may contain fluoride in excess of the Environmental Protection Agency's (EPA's) safe limit for infants. Our analyses show that infants drinking between one and two 8-ounce bottles daily of powdered formula reconstituted with Nursery Water's bottled water would be exposed to fluoride at levels that exceed the EPA's safe dose for infants, established to protect against fluorosis (EPA 1989). Of further concern, a 2007 review published in *The Lancet* listed fluoride as one of three emerging developmental neurotoxins (Grandjean and Landrigan 2007), and a 2006 National Research Council review raised concerns about fluoride's potential impacts to the thyroid gland and IQ, with measured effects in some studies at fluoride levels below those added by Nursery Water (NRC 2006). To

our knowledge, Nursery Water provides no warnings to parents about potential risks from infants' exposures to fluoride.

Overall, our review of Nursery Water advertising materials suggests that the company is providing parents with advertising information about the benefits of fluoride-containing water for infants that is misleading, erroneous, and appears to be in violation of the exclusion of fluoride-related health claims for water marketed for infants published by the Food and Drug Administration (FDA 2006), health claim notification requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Federal Trade Commission Act's (FTCA) prohibition on the dissemination of false advertisements (21 U.S.C. §52).

These advertising materials are likely to lead a reasonable person to mistakenly believe that adding fluoridated bottled water to formula strengthens teeth and prevents cavities without risk, when, in fact, there is significant scientific agreement that fluoridated water increases infants' risk of fluorosis. Because of the potential ill effects and the egregious nature of these misleading advertisements, we call on the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) to investigate immediately the improper fluoride health claims made by Nursery Water, to enforce restrictions on such claims for bottled water marketed for infants, to enjoin the company from making further misleading health claims, and to pursue other appropriate legal remedies. We also request that FDA publicly release the identity of the clients represented by Covington & Burling LLP in the law firm's health claim notification for fluoride in bottled water and in the firm's subsequent clarification of the claim's exclusion for bottled water marketed to infants (Covington & Burling 2006a,b). Lastly, we request that FDA release all communications between the agency and Covington & Burling regarding the health claim notification.

**Potential Violation: Use of Excluded Fluoride Health Claims for Bottled Water Marketed to Infants.** As you are aware, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires manufacturers to submit a Health Claim Notification to FDA prior to using a health claim, and provides FDA with authority to deny the claim via regulation. Pursuant to this, FDA recently published an allowable notification for a claim regarding dental benefits of fluoride that specifically excludes its use on bottled water marketed for infants (FDA 2006). Nursery Water markets its bottled water for infants, and makes direct or strongly implied health claims regarding added fluoride in water, despite the specific exclusion published by FDA.

The Notification for a Health Claim for fluoride in bottled water was submitted to FDA on June 14, 2006 by the law firm Covington & Burling LLP. The notification proposed to allow bottled water containing between 0.6 and 1.0 ppm (parts per million) fluoride to bear the following claim: "Drinking fluoridated water reduces the risk of [dental caries or tooth decay]" (Covington & Burling 2006a). The original submission for a health claim notification included discussion of fluoride's benefits during infancy, before teeth have erupted through the gum.

On October 3, 2006, 11 days before the deadline for FDA action, the firm modified its claim. The revised proposed claim contained the qualifier "may": "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." And, Covington & Burling LLP specifically stated in its proposed revision that the health claim would not be made on bottled water products marketed for use by infants: "In addition, this health claim is not intended for use on bottled water products specifically marketed for use by infants" (Covington & Burling 2006b).

The claim became legal for use as proposed on October 14, 2006, 120 days after submission, the waiting period prescribed in FFDCA (403(r)(3)(C) (21 U.S.C. §343(r)(3)(C)). As FDA notes,

the claim is now allowed for use on all bottled water *except* that marketed specifically to infants (FDA 2006). Nevertheless, Nursery Water makes or implies health claims in the advertising materials they provide to parents about their water, marketed for infants, with added fluoride. Details of specific claims made are provided in this letter.

**Potential Violation: Requirement for Health Claim Notification under FFDCFA.** In light of the published exclusion on fluoride health claims for bottled water marketed to infants, the Federal Food Drug and Cosmetics Act (FFDCA) (21 U.S.C. §343(r)(3)(C)) would require companies marketing fluoridated bottled water to infants like Nursery Water to submit a new Health Claim Notification to FDA prior to making any such claims. To the best of our knowledge, the company has not submitted this required Notification in advance of claiming or strongly implying dental benefits for infants consuming water with added fluoride.

Among Nursery Water's claims are: "the added fluoride will help strengthen your little one's teeth," and "Specially formulated to contain the ADA recommended level of added fluoride, the steam distilled water helps to strengthen teeth."

**Nursery Water's advertising of health benefits from fluoride in bottled water.**

Nursery Water, manufactured by DS Waters of America, Inc., is a popular brand of bottled water that is specifically marketed for infants and toddlers. In their online advertising materials ([www.nurserywater.com](http://www.nurserywater.com)), the company makes multiple direct or indirect claims of the health benefits of fluoride for infants and toddlers, that appear to be in direct violation of the health claim exclusion. In addition, the company's marketing materials contain numerous implied claims about the prevention of tooth decay. The company also misrepresents the views on fluoride safety of the AAP, CDC, and ADA.

All claims appear on web pages with a prominent banner featuring a photograph of an infant and the words "A first step to your baby's good health. Since 1948. Nursery purified water with added fluoride processed by steam distillation," and a lower banner, also prominently featuring another infant photo with the words "pure love for your infant & toddler." The navigation menu on the left-hand side of the page lists "mixing with formula," "dental care," and "tooth decay" under the heading "Nursery for infants." The juxtaposition of health statements with infant photographs, and the words "health," "fluoride," "dental care," and "tooth decay" appearing together prominently on each page amplifies the implied and direct health claims. Health claims and misrepresentations in Nursery Water advertising materials are outlined below, with all emphases added:

- The primary purpose in adding fluoride to distilled drinking water is to **help strengthen teeth**. Nursery Water is a purified water that is steam distilled for purity. **Drinking distilled water with added fluoride in the proper amounts has been shown to be so effective that the ADA supports municipal water fluoridation and refers to this as the single most effective measure to prevent tooth decay. This has also been endorsed by the Center for Disease Control and Prevention, labeling municipal water fluoridation as one of the greatest public health achievements of the 20<sup>th</sup> century.** ([www.nurserywater.com/nursery/fluoride.php](http://www.nurserywater.com/nursery/fluoride.php))
- "Nursery is a steam distilled water for babies from **infants** to toddlers... that has **added fluoride up to the recommended ADA level** of 0.7 ppm... a **healthy** source of steam distilled water for babies, infants, and toddlers." ([www.nurserywater.com/info/about.php](http://www.nurserywater.com/info/about.php))

- **“Prevention of tooth decay... “Give his/her [stet] enough fluoride.** If your local water supply does not contain fluoride, ask your dentist how your child should get it.” ([www.nurserywater.com/infants/care.php](http://www.nurserywater.com/infants/care.php))
- “...we are happy to provide you with Nursery that is purified water with added fluoride processed by steam distillation that **will do much more than simply hydrate your child.** Specially formulated to **contain the ADA recommended level of added fluoride,** the steam distilled water **helps to strengthen teeth.**” ([www.nurserywater.com](http://www.nurserywater.com))
- “Nursery Water is a purified water with added fluoride that is processed by steam distillation that **will help nourish** your infant or toddler.” ([www.nurserywater.com](http://www.nurserywater.com))
- “Nursery for Infants: A first step to your baby’s good health... Since 1948, Nursery Purified Water with added Fluoride, processed by steam distillation, has been **trusted by new mothers like you for mixing with infant formulas,** diluting juices and as a good source of pure drinking water. Nursery is a **convenient source of fluoride** and is available in economical one gallon bottles. You’re doing everything you can to give your baby a **healthy start in life.** Trust Nursery as an important part of your plan during those precious infant years. ([www.nurserywater.com/infants](http://www.nurserywater.com/infants))
- “Nursery... comes in convenient one gallon bottles so it’s easy to keep a supply on hand for **mixing with cereals and formulas.** Remember, **ready-to-feed formula does not contain fluoride,** so if you use it on a regular basis, you may want to consider **supplementing your little one’s diet with Nursery purified water with added fluoride.**” ([www.nurserywater.com/infants/usage.php](http://www.nurserywater.com/infants/usage.php))
- “...the proper amount of **fluoride has been added for your child.** Nursery Water follows the strict guidelines set forth by the **ADA recommending the optimal fluoride level** in drinking water is 0.7 – 1.2 parts per million (ppm) of fluoride for infants.” ([www.nurserywater.com/infants/usage.php](http://www.nurserywater.com/infants/usage.php))
- “Natural benefits.... Nursery can be ideal for **mixing with formula** since it is distilled and **contains the fluoride your baby may need.**” ([www.nurserywater.com/infants/bfeed.php](http://www.nurserywater.com/infants/bfeed.php))
- “Drinking our purified and steam distilled water has **many benefits for your little one. The added fluoride will help strengthen your little one’s teeth...** You can use Nursery for many purposes: from **mixing with formula** and cereals to diluting juices or simply using Nursery as your child’s drinking water.” ([www.nurserywater.com/nursery/product.php](http://www.nurserywater.com/nursery/product.php))
- **“Is fluoride in water safe for my child? Yes.** According to the ADA, having fluoride in the water you drink is safe between the levels of 0.7 – 1.2 parts per million (ppm). Nursery steam distilled drinking water contains up to 0.7 ppm, well **within ADA recommendations.** This means **when your child is drinking Nursery Water you can be sure that they are getting the proper level of fluoride...**” ([www.nurserywater.com/nursery/fluoride.php](http://www.nurserywater.com/nursery/fluoride.php))
- **“Is drinking water with fluoride safe for my child? Yes. The American Dental Association continues to support the optimal level of fluoride** in drinking water as 0.7 – 1.2 parts per million (ppm). Nursery Waters has a level up to 0.7 parts per million –

well ***within ADA recommendations***. This means that ***when your child is drinking Nursery Water, you can be confident that your child is getting the right level of fluoride...*** Fluoride, in the amount of up to 0.7 mg/L is added, which conforms to fluoride levels ***recommended by American Dental Association.***  
([www.nurserywater.com/info/faq.php](http://www.nurserywater.com/info/faq.php))

**False advertising: affirmative deceptive statements.** The FTC has jurisdiction over false advertising of health claims under FTCA section 5 (21 U.S.C. §52), pursuant to a Memorandum of Understanding with FDA under which FTC assumes primary responsibility for regulating food advertising, with FDA taking primary authority for food labeling (FTC and FDA 1971).

Despite the specific exclusion of health claims regarding the benefits to infants from fluoride in bottled water, Nursery Water has published extensive, misleading advertising in online materials. This appears to be an intentional attempt at circumventing FDA's health notification process by placing in its advertising materials misleading claims that it cannot place on its labels in violation of FTCA.

FTC has stated that companies cannot expect to evade requirements for health claim notification and substantiation by limiting health claims to advertising materials.

On this point FTC has written that:

"The Commission also recognizes the importance of the petition process, established under the NLEA and FDA's regulations, as a mechanism for authorizing health claims in food labeling. The Commission will look with particular care at any health claims specifically considered by the FDA in the process. The absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission's assessment of the adequacy of substantiation for the claim. Food marketers should not expect to circumvent FDA's petition process for health claims simply by limiting the assertion of unapproved or unreviewed claims to advertising" (FTC 2004).

Despite FDA's specific exclusion of infants from the Health Notification, Nursery Water appears to be circumventing the petition process by the assertion of unapproved claims in advertising. Nursery Water appears to be publishing false advertising in the form of affirmative, deceptive statements and presentation of information, and in its misrepresentation of ADA, CDC, and AAP positions on the safety of fluoride for infants.

Nursery Water mentions ADA's support of water fluoridation multiple times in its online marketing materials, citing ADA positions to support the safety of fluoride in water for children, and making numerous mentions that Nursery water contains (or contains "up to") the ADA's "recommended" level of fluoride. Nursery Water references a 2006 ADA position paper in making these claims (ADA 2006). But instead of advocating for added fluoride in water for infants, ADA recommends against it in its 2006 position paper. ADA notes that while "the ***occasional*** use of water containing optimal levels of fluoride should not appreciably increase a child's risk for fluorosis," [emphasis added], "ready-to-feed formula is preferred," since it typically contains no added fluoride, and that concentrated or powdered formula "can be mixed with water that is fluoride free" or that contains little to no fluoride, such as water that is "purified, demineralized, deionized, distilled, or reverse osmosis filtered water." ADA does not recommend that infants drink water with added fluoride.

Likewise, Nursery Water notes in advertising materials that CDC “endorses” water fluoridation ([www.nurserywater.com/nursery/fluoride.php](http://www.nurserywater.com/nursery/fluoride.php)), but fails to mention that CDC does not recommend that infants drink water with added fluoride, because of the risk of fluorosis (CDC 2007). CDC notes that while “mixing concentrate with fluoridated tap water on an **occasional basis** is unlikely to be of much consequence” [emphasis added], “parents and caregivers of infants fed primarily with formula from concentrate... can lessen [fluoride] exposure by mixing formula with low fluoride water most or all of the time,” such as bottled water known to be low in fluoride, including water labeled as “purified, deionized, demineralized, distilled, or prepared by reverse osmosis” (CDC 2007). CDC writes that:

- “Infant formula manufacturers take steps to assure that infant formula contains low fluoride levels—the products themselves are not the issue. Although formula itself has low amounts of fluoride, **when infant formula concentrate is mixed with fluoridated water and used as the primary source of nutrition, it may introduce fluoride at levels above the amount recommended to minimize the risk for fluorosis**” (CDC 2007).
- “Mixing concentrate with fluoridated tap water on an occasional basis is unlikely to be of much risk. **However, when used consistently as the primary source of nutrition over longer periods of the first year, a child may receive enough fluoride to increase his/her chances of developing very mild or mild fluorosis**” (CDC 2007).

CDC has found that 32 percent of children and young adults ages 6 to 19 have some degree of fluorosis (CDC 2005a,b). CDC does not recommend that infants drink water with added fluoride.

Nursery Water’s advertising claims that their product is “Made according to recommendations by the American Academy of Pediatrics (AAP)” ([www.nurserywater.com/infants/bfeed.php](http://www.nurserywater.com/infants/bfeed.php)), but the AAP takes the position that “**Supplementary fluoride should not be provided during the first 6 months of life**” (AAP 2005).

Clearly, the ADA, CDC, and AAP recognize the risk of enamel fluorosis in infants who are fed formula that is mixed with fluoridated water. These organizations advise that parents minimize their infants’ daily exposure to fluoride, while Nursery Water marketing materials clearly encourage the use of fluoride-supplemented bottled water for infants. Nursery Water’s misrepresentation of ADA, CDC, and AAP positions on its website may constitute affirmative, deceptive advertising.

**False advertising: deceptive advertising that omits material facts likely to mislead consumers.** FTC has also stated that in addition to affirmative deceptive statements, it will also consider deceptive advertising that omits material facts likely to mislead consumers. In assessing health claims, FTC defers to FDA expertise (FTC and FDA 1971). Nursery Water publishes advertising information on dental benefits and risks of fluoride for infants that omits material facts and could mislead parents about the benefits and risks of fluoride for infants. Most notably, Nursery Water fails to inform parents and caregivers about the increased risks for fluorosis faced by infants who are dosed with fluoride.

It is notable that Covington & Burling proposed an exclusion to dental health claims on fluoridated bottled water marketed to infants (Covington & Burling 2006b), and that FDA included this exclusion in its summary of the Health Claim Notification (FDA 2006). This

exclusion is supported by the science on fluoride risks and benefits, none of which, to our knowledge, is cited in Nursery Water advertising materials.

**Infants' elevated risk for fluorosis.** Nursery Water claims or implies in its marketing materials that the ADA, CDC, and AAP support the addition of fluoride to water consumed by infants. In fact, experts have taken the opposite position regarding the benefits of fluoride for infants than that represented in the companies' advertising materials. While not placing the claim on the labeling, Nursery Water places it in their advertising materials, an apparent attempt to skirt the law and a violation of the FTC's prohibition on the dissemination of false advertisements (21 USC §52).

Both ADA and CDC have raised questions or published warnings about the risks of fluoride for infants, driven by their susceptibility to fluoride-induced damage to tooth enamel called fluorosis, a defect of the permanent teeth resulting in dark staining and, in severe cases, substantial corrosion of the enamel.

The development of permanent teeth begins at infancy with initial calcification of the first molars under the gum. Infants are particularly susceptible to fluorosis from fluoride exposure. Enamel fluorosis occurs when there is hypomineralization of tooth enamel; it results from excessive fluoride intake during tooth development. Infants are vulnerable to enamel fluorosis because of rapid tooth development during this critical period. Enamel fluorosis can affect both primary and permanent teeth. While most cases are considered mild in severity, the aesthetic effects that result include pitting, staining, and opacity of the enamel (Pizzo et al. 2007). While the mechanism of fluorosis development is not fully understood, it is thought that fluoride interferes with normal protein metabolism, leading to altered tooth structure (Marshall et al. 2004). Children remain at risk for fluorosis throughout childhood as tooth formation continues, though risks are particularly high during infancy.

In a recent report based on National Health and Nutrition Examination Survey (NHANES) results, 32% of children and adolescents aged 6 to 19 years were found to suffer from the condition (Beltran-Aguilar et al. 2005).

Recent reports in the peer-reviewed literature have highlighted the relationship between the development of enamel fluorosis and the use of fluoridated water for infants (Beltran-Aguilar et al. 2005, Levy 2003, Browne et al. 2005, Marshall et al. 2003, Warren and Levy 1999, Hong et al. 2006). As one example of findings from these studies, Hong et al. (2006) studied fluoride exposures of 579 children in Iowa, and found that fluoride exposures during the first year of life were the most strongly linked to the development of fluorosis of the two front teeth, followed by exposures during the second, third and fourth years of life.

Formula manufacturers voluntarily decreased the use of fluoride in their products in the 1970's because of the risk of fluorosis from the use of their products. However, with the increasing popularity of powdered infant formulas, the use of fluoridated water to reconstitute these products has come under scrutiny. One recent study from scientists at the University of Iowa concluded, "Infants beverages, particularly infant formulas prepared with fluoridated water, can increase the risk of fluorosis" (Marshall et al. 2004).

Nursery Water fails to inform parents about infants' risks for fluorosis, or that infants drinking Nursery Water's bottled water can be exposed to fluoride above levels established by the Environmental Protection Agency to protect children from fluorosis. The EPA has recommended that to protect against dental fluorosis, infants be exposed to no more than 0.06 milligrams of



fluoride per kilogram of body weight per day (0.06 mg/kg/d) (EPA 1999). EWG's analyses show that a newborn would be exposed to fluoride above this limit by drinking just over one bottle of formula reconstituted with Nursery Water each day.

Our calculations show that a newborn of average weight (7.3 pounds) drinking just 12 ounces of powdered formula reconstituted with Nursery Water's bottled water would be exposed to fluoride in excess of the EPA's safe daily dose to protect infants from fluorosis (0.06 milligrams of fluoride per kilogram of body weight (EPA 1989), assuming Nursery Water's published upper limit of 0.7 ppm added fluoride in the water ([www.nurserywater.com](http://www.nurserywater.com)) and 12% adjustment for solids content). The levels of fluoride added to water by Nursery Water would lead to many babies being exposed to fluoride above EPA's safe dose beginning at birth and continuing throughout infancy.

**Efficacy of fluoride to dental health from exposures during infancy.** In addition to demonstrated elevated fluorosis risks associated with exposures during infancy, studies also raise serious questions about the efficacy of fluoride dosing in early life. The value of fluoride in maintaining dental health is clear, but some studies now demonstrate that fluoride may confer little to no resistance to cavities when dosing occurs in infancy, before the teeth erupt from the gum (Fejerskov 2004, Hellwing and Lennon 2004, Limeback 1999).

Studies demonstrate that fluoride's primary action in cavity prevention derives from enhanced tooth mineralization after topical application (Featherstone 2000 & Fejerskov 2004). Fluoride's antimicrobial action on the surface of the teeth is also thought to play a role. But fluoride that is swallowed and incorporated systemically into tooth enamel was not proven to have a significant effect in preventing cavities (Featherstone 1999). An increasing body of research supports the view that in developed countries with populations that practice good oral hygiene, fluoridated water may be unnecessary and, additionally, may present serious health risks (e.g., Pizzo et al. 2007, NRC 2006, Rocha-Amador et al. 2007, Wang et al. 2007).

**Other potential health impacts of fluoride.** As noted previously, potential health impacts from ingestion of fluoride extend beyond fluorosis to encompass other impacts as well. A March 2006 report from the National Academy of Sciences' National Research Council (NRC 2006) identified fluoride as a potent hormone disruptor that may affect normal thyroid function. Fluoride's potential to impair thyroid function is most clearly illustrated by the fact that until the 1970s, European doctors used fluoride as a thyroid-suppressing medication for patients with hyperthyroidism. Infants are especially vulnerable to any disruption of thyroid function because adequate thyroid hormone levels are critical to normal growth and development.

The National Academy of Sciences' (NAS) National Research Council (NRC) has raised further questions about additional risks fluoride poses during development based on studies demonstrating elevated rates of bone cancer (osteosarcoma), IQ reduction, thyroid disruption, and other impacts linked to fluoride exposure (NRC 2006). In particular, the NRC report cited concerns about the potential of fluoride to lower IQ, noting that the "consistency of study results appears significant enough to warrant additional research on the effects of fluoride on intelligence." Additional studies published since the NRC review provide further support for fluoride's impacts on children's IQ (e.g., Rocha-Amador et al. 2007, Wang et al. 2007). That NRC finding was echoed by a December 2006 study published in the prestigious peer-reviewed journal *The Lancet* that identified fluoride as an "emerging" neurotoxin (Grandjean and Landrigan 2006).

**Recommendations.** Because of the apparently intentional attempts to skirt FDA and FTCA law and the potentially significant adverse health effects to infants, we urge FDA and FTC to:

- investigate expeditiously the improper use of health claims in advertising materials published by Nursery Water on the benefits of added fluoride in bottled water for infants;
- enforce restrictions on such claims for bottled water marketed for infants;
- release the names of the clients Covington & Burling was representing in its Health Claim Notification and all communications between the agencies and Covington & Burling regarding the health claim notification for fluoride;
- enjoin the company from making further misleading health claims; and
- pursue other appropriate legal remedies.

Nursery Water's materials appear to intentionally mislead consumers on the threat fluoride poses to infants and the positions of the Centers for Disease Control and Prevention, the American Dental Association, the American Academy of Pediatrics, the Environmental Protection Agency, and the National Research Council of the National Academy of Sciences, all of whom have recognized the unique risks fluoride exposures can pose during infancy. This appears to be an attempt to circumvent legal requirements to convince consumers to purchase their product without knowledge of the potential risks to infants.

Sincerely,

[signed]

Anila Jacob, M.D., M.P.H.  
Senior Scientist

[signed]

Jane Houlihan  
Vice President for Research

**Cc:** Deborah Platt Majoras, Chair, Federal Trade Commission  
Pamela Jones Harbour, Federal Trade Commission  
Jon Leibowitz, Federal Trade Commission  
William E. Kovacic, Federal Trade Commission  
J. Thomas Rosch, Federal Trade Commission

## **ATTACHMENT**

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- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us

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Nursery® Water is a purified water with added fluoride that is processed by steam distillation that will help nourish your infant or toddler. Our water goes through an extensive process of steam distillation to ensure that it is safe and of the highest quality to assist in the growth and development of your little one. We even add minerals such as magnesium, potassium, and calcium for a refreshing taste your child will love! Once Nursery® Water goes through the purification process, we conduct routine monitoring to ensure that it is of the highest quality.

We understand that as a new parent, you are concerned with taking the best possible care of your child. This is why we are happy to provide you with Nursery® that is purified water with added fluoride processed by steam distillation that will do much more than simply hydrate your child. Specially formulated to contain the ADA recommended level of added fluoride, the steam distilled water helps to strengthen teeth. We also provide you with a wealth of information on ways you can help keep your child healthy and happy during the critical first years of development.

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- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us



**POSTNATAL MONTHS**  
1 2 3 4 5 6 7 8 9 10 11 12 13 thru 18 19 thru 24

**BIRTH**  
A B

**PRENATAL MONTHS**  
1 2 3 4 5 6 7 8 9

**Nursery® for Infants: A first step to your baby's good health**

Since 1948, Nursery® Purified Water with added Fluoride, processed by steam distillation, has been trusted by new mothers like you for mixing with infant formulas, diluting juices and as a good source of pure drinking water. Nursery® is a convenient source of fluoride and is available in economical one gallon bottles. You're doing everything you can to give your baby a healthy start in life. Trust Nursery® as an important part of your plan during those precious infant years.

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- Mixing With Formula
- Diluting Juices
- As Drinking Water

**Dental Care**

- Baby Teeth Formation
- Baby Bottle Tooth Decay

**Breastfeeding**

- Natural Benefits
- Important Fluids

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**More**

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- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us

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**Why is Using Distilled Water for Infant Formula Important to Your Child's Health?**

The primary purpose for using distilled water for infant formula that is purified is for safety. Because your baby does not yet have a fully developed immune system, it is important to use safe distilled water for baby formula <sup>1</sup>. Many pediatricians recommend either boiling water for infant formula or using bottled distilled water, which can be more convenient. Nursery® is a purified water that is processed by steam distillation for purity and comes in convenient one gallon bottles so it's easy to keep a supply on hand for mixing with cereals and formulas. **Remember, ready-to-feed formula <sup>2</sup> does not contain fluoride, so if you use it on a regular basis, you may want to consider supplementing your little one's diet with Nursery® purified water with added fluoride.**

**Choosing between boiling water and using safe distilled water for baby formula.**

Many parents might wonder why they should use a safe distilled water for baby formula as opposed to boiling their own water. This is simply because boiling water, although it will remove some impurities, may leave behind many others <sup>3</sup>. Nursery® Water makes sure that when you use steam distilled water for baby formula, not only has it gone through a stringent purification process, but that the proper amount of fluoride has been added for your child. Nursery® Water follows the strict guidelines set forth by the ADA recommending the optimal fluoride level in drinking water is 0.7 - 1.2 parts per million (ppm) of fluoride for infants <sup>4</sup>. The refreshing taste of Nursery® Water due to the extensive purification process will provide an added bonus as your child is sure to enjoy it.

**PREMATURAL MONTHS**

1 2 3 4 5 6 7 8 9 B 1 2 3 4 5 6 7 8 9 10 11 12 13 thru 18 19 thru 24

**BIRTH**

**POSTNATAL MONTHS**

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- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners



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PRENATAL MONTHS

1 2 3 4 5 6 7 8 9

BIRTH

B 1 2 3 4 5 6 7 8 9

POSTNATAL MONTHS

10 11 12 13 thru 18 19 thru 24

**Baby Teeth Formation**

Your infant's healthy start should include proper dental care. Just because you can't see those little teeth yet doesn't mean they aren't there. Teeth start forming during the second trimester, so at birth, your baby could have 20 primary teeth.<sup>3</sup>

**Prevention of Tooth Decay**

Prolonged contact with almost any liquid other than water can cause something called baby bottle tooth decay (BBTD). Putting your baby to bed with a bottle of formula, milk, juice, soda or sugar water is one cause; giving him sweet drinks several times a day is another. Liquid from the bottle builds up in the mouth, the natural or added sugars change to acid and the acid starts dissolving the teeth, causing them to decay. BBTD can severely damage baby teeth and can also affect permanent teeth. To help prevent it, consider these tips:

- Never let your child fall asleep with a bottle of milk, formula, fruit juice or sweetened liquid. If he needs to be comforted between feedings, give him a clean pacifier recommended by your doctor or dentist. Never give him a pacifier dipped in sweet liquid.
- Teach your child to drink from a cup as early as possible. Usually by one year of age, children can drink from a cup, which keeps liquid from collecting around the teeth. And, cups can't be taken to bed.
- Keep your baby's mouth clean. Gently wipe his/her gums with a clean gauze pad after feedings.
- Brush baby teeth with water and a soft child-sized toothbrush. Start brushing as soon as the first tooth erupts, and flossing when all the baby teeth are in.
- By the time your toddler is two years of age, you should brush his/her teeth once or twice a day. Try to brush after breakfast and before bedtime. Once you're sure she can spit the toothpaste out instead of swallowing it, use pea-sized amounts of fluoride toothpaste.
- Give his/her enough fluoride. If your local water supply doesn't contain fluoride, ask your dentist how your child should get it.
- Take your child to the dentist by age one. Start earlier if you think she has dental problems, then visit regularly.<sup>9</sup>

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**Nursery for Infants**

- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us



**What is Baby Bottle Tooth Decay?**

Baby bottle tooth decay (also known as baby bottle tooth) is a condition that occurs when sweet liquids are allowed to have frequent contact with your baby's teeth. A common cause of this ailment is putting your baby to bed with a bottle of formula, milk, juice, soda, or sugar water. This can also be caused by giving your child several sweet drinks throughout the day. According to the ADA, "As soon as a baby's first teeth appear, usually by age six months or so, the child is susceptible to decay."<sup>1</sup>

Treatment of baby bottle tooth decay varies greatly, from fluoride application to full coverage of teeth with stainless steel or veneered crowns, depending on the progression of the decay. It is best to contact your pediatric dentist as soon as possible to evaluate your child's risk.

**How you can help to prevent baby bottle tooth decay?**

Baby bottle tooth decay is a very serious condition; however, there are several ways in which you can prevent the disease from taking place. Prevention methods for infants range from teaching your child to drink from a cup at an early age, cleaning his/her mouth after feedings, brushing at the first sign of teeth, and using a clean pacifier as opposed to a bottle to calm your baby between feedings.

Prevention of baby bottle tooth decay does not stop with toddlers. You should brush your child's teeth twice a day and make sure that your child receives enough fluoride. If your local municipal water does not contain fluoride, contact your dentist to ask how your child can get it.

Consult your physician or dental professional if using another fluoridated product.

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**POSTNATAL MONTHS** 10 11 12 13 thru 18 19 thru 24

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**Nursery for Infants**

- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us

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1 2 3 4 5 6 7 8 9 10 11 12 13 thru 18 19 thru 24

**BIRTH**

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**PRENATAL MONTHS**

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**Natural Benefits**

Breast milk contains the best possible combination of nutrients for your baby, and for the first four to six months of life, he/she probably won't need anything else. It's easy for him/her to digest, it helps fight infections and it can limit his exposure to potential allergens.<sup>13</sup>

If you make the choice not to breastfeed, you can still give your baby all the nutrients he/she needs with commercial formula. **Made according to recommendations by the American Academy of Pediatrics (AAP) and the Food and Drug Administration (FDA), formula is a good substitute for the real thing.**<sup>14</sup> **Nursery® can be ideal for mixing with formula since it is distilled and contains the fluoride your baby may need.**

**Important Fluids**

Most babies need about one and one-half ounces of fluid for each pound of body weight. Although they usually get the amount they need from breast milk or formula, there may be times when they need more.<sup>15</sup> Pure, fresh Nursery® Water can be a healthy addition to your little one's diet.

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<sup>13</sup> "The Benefits of Breastfeeding," [www.drspock.com](http://www.drspock.com)

<sup>14</sup> "An Overview of Infant Formulas," [www.drspock.com](http://www.drspock.com)

<sup>15</sup> "How to Tell If Your Infant is Getting Enough Fluids," [www.drspock.com](http://www.drspock.com)

**Note: Emphasis added**

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 A child's birthday is a very special occasion and many parents can't wait to throw the biggest bash on the block to celebrate. Before sending out the invitations, however, it's a good idea to think about what will make your toddler's birthday party an event you'll all want to remember.

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**Why is Nursery® a purified water processed by steam distillation?**  
 Nursery® is made with distilled water that is processed by steam distillation, purified with added fluoride. Drinking our purified and steam distilled water has many benefits for your little one. The added fluoride will help strengthen your little one's teeth while our process of steam distillation assures you that it is safe, pure, clean, and healthy. Our product is conveniently available in economical one gallon bottles or Nursery® Sesame Street® easy-to-hold buddy bottles. You can use Nursery® for many purposes: from mixing with formula and cereals to diluting juices or simply using Nursery® as your child's drinking water.

**The purity of drinking our distilled water.**  
 Because we understand that drinking distilled water is extremely important to ensuring your child stays healthy and safe, our product goes through a stringent purification process. The process starts with filtration where impurities are removed. Followed by steam distillation, resulting in a drinking water in its purest form. Next, minerals like fluoride, magnesium, calcium, and potassium are added back to Nursery®, giving the water a pure fresh taste. Finally, micron filtration ensures clarity and product quality. The last step is ozonation which disinfects the water.

After this process, not only is our product tested and inspected by the FDA (Food and Drug Administration) and other third party organizations such as the NSF (National Sanitation Foundation); we at Nursery® test all of our products made with distilled water to ensure that they are of the highest possible quality for your child.

**Why for Infants**  
 ing With Formula  
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 astfeeding

**Why for Toddlers**  
 Age  
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 ntal Care


**Why Information**  
 Product  
 oride and Your Child  
 ld Dehydration Facts

**onal Information**  
 out Us  
 ere to Buy  
 r Neighborhood  
 r Partners  
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**Nursery for Infants**

- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**

- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us

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**Is fluoride in water safe for my child?**

Yes. According to the ADA, having fluoride in the water you drink is safe between the levels of 0.7 - 1.2 parts per million (ppm). Nursery® steam distilled drinking water contains up to 0.7 ppm, well within ADA recommendations. This means when your child is drinking Nursery® Water you can be sure that they are getting the proper level of fluoride.

Other sources that contain fluoride supplements, according to the ADA, are fluoride toothpaste, fluoride mouth rinse, doctor prescribed fluoride dietary supplements, or naturally occurring fluoride in drinking water.


**What is the purpose of adding fluoride to distilled drinking water?**

The primary purpose in adding fluoride to distilled drinking water is to help strengthen teeth. Nursery® Water is a purified water that is steam distilled for purity. Drinking distilled water with added fluoride in the proper amounts has been shown to be so effective that the ADA supports municipal water fluoridation and refers to this as the single most effective measure to prevent tooth decay. This has also been endorsed by the Center for Disease Control and Prevention, labeling municipal water fluoridation as one of the greatest public health achievements of the 20th century. <sup>1</sup>

<sup>1</sup> [http://www.fluorideinfo.org/kids\\_effectiveness.html](http://www.fluorideinfo.org/kids_effectiveness.html)

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**Nursery for Infants**

- Mixing With Formula
- Dental Care
- Baby Bottle Tooth Decay
- Breastfeeding

**Nursery for Toddlers**

- Usage
- Cavity Prevention
- Dental Care

**Nursery Information**

- The Product
- Fluoride and Your Child
- Child Dehydration Facts

**Additional Information**


- About Us
- FAQ
- Where to Buy
- Your Neighborhood
- Our Partners
- Contact Us

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**Nursery® is a steam distilled water for babies from infants to toddlers**

Nursery® is a purified water processed by steam distillation for babies and toddlers, that has added fluoride up to the recommended ADA level of 0.7ppm. Baby drinking water by Nursery® was created in 1948 by Dr. Herman Bundason, then Director of the Chicago Health Department. Bundason was concerned about the sterility of municipal drinking water when it was used to mix infant formulas both in hospitals and in homes. Today, Nursery® Water continues its commitment to purity by continuously evaluating and monitoring our water so you'll have peace of mind in knowing that you will always have a healthy source of steam distilled water for babies, infants, and toddlers.

**Producing healthy and safe baby drinking water for over 50 years**

For over 50 years now Nursery has been able to offer a source of safe water for your baby. Drinking water is essential to their health and growth and Nursery® recognizes how important your baby is to you. This is why our steam distilled water for babies and toddlers contains added minerals and goes through a rigorous steam distillation process. Over time, our company has grown to help extend our reach to more and more consumers and to share our great product with families like yours. Nursery® is a product of DS Waters of America, Inc, a producer and distributor of home, office and retail bottled water products across the United States under the brand names of Alhambra®, Belmont Springs®, Crystal Springs®, Hincley Springs®, Kentwood Springs®, Nursery® Water, Sierra Springs® and Sparklets®, and Roast2Roast®, a coffee delivery service. The company, headquartered in Atlanta, Georgia, is the U.S. leader in home and office water delivery, focusing on five gallon, one gallon and single serve bottled water products. Water is bottled at 25 manufacturing facilities and then delivered to millions of homes and offices, as well as retail establishments across the country. DS Waters employs approximately 4,500 associates in 40 states.

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- Nursery for Infants**
  - Mixing With Formula
  - Dental Care
  - Baby Bottle Tooth Decay
  - Breastfeeding
- Nursery for Toddlers**
  - Usage
  - Cavity Prevention
  - Dental Care
- Nursery Information**
  - The Product
  - Fluoride and Your Child
  - Child Dehydration Facts
- Additional Information**
  - About Us
  - FAQ
  - Where to Buy
  - Your Neighborhood
  - Our Partners
  - Contact Us

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**Frequently Asked Questions**

**Is drinking water with fluoride safe for my child?**

Yes. The American Dental Association continues to support the optimal level of fluoride in drinking water as 0.7 - 1.2 parts per million (ppm). Nursery Waters has a level up to 0.7 parts per million - well within ADA recommendations. This means that when your child is drinking Nursery Water, you can be confident that your child is getting the right level of fluoride.

For full information or a copy of the ADA November 9th, 2006 Interim Guidance on Fluoride Intake for Infants and Young Children, please log onto: [http://ada.org/prof/resources/positions/statements/fluoride\\_infants.asp](http://ada.org/prof/resources/positions/statements/fluoride_infants.asp)

[Back to Top](#)

**Does Nursery® Water have to be refrigerated?**

Refrigeration of Nursery® Water is not required prior to or after opening. Always make sure to replace the cap after opening and put the unused portion aside on a kitchen counter. Never store the water near solvents (like cleaning supplies) or food with strong odors. Also, do not store Nursery® Water in direct sunlight.

**What makes Nursery® Water special?**

Nursery® Water is steam distilled water with added fluoride. Nursery® Water can be mixed directly with formula (refer to formula label instructions) or put in a bottle.

Nursery® Water uses DISTILLED WATER as its base. Distilled water is produced by filtering source water through sand and activated carbon to remove chlorine, unpleasant taste and odor as well as sediment and trihalomethanes. This filtered water is converted to steam in a stainless steel distiller. Dissolved contaminants are left behind as the water is vaporized and condensed. The water is then bottled after being filtered through one-micron filters and ozonated. Fluoride, in the amount of up to 0.7 mg/L is added, which conforms to fluoride levels recommended by American Dental Association (ADA).

### **Why are minerals added to Nursery® Water?**

Calcium, magnesium and potassium are added for taste. At the levels used, they do not provide any nutritional benefits.

[Back to Top](#)

### **At what age can infants be given Nursery® Water?**

According to Pediatricians, if a mother is NOT breastfeeding and is using powdered formula, Nursery® Water can be mixed directly with formula and given to infants from birth. Refer to the formula instructions or consult your Pediatrician for feeding instructions.

If using Nursery® Water only to supplement feeding, this can normally begin at six months. Again, consult with your Pediatrician.

[Back to Top](#)

### **Since Nursery® Water is distilled, is it sterile?**

No. Nursery® Water, like any bottled water, is not considered sterile.

[Back to Top](#)

### **Why is my bottle of Nursery® Water discolored or have mold?**

In most cases, discoloration is caused when particles of formula inadvertently enter the bottle of Nursery® Water when preparing your child's bottle. When mixing Nursery® Water with formula, it is important that you pour the water into a clean bottle first and then add the correct amount of formula. Formula particles that enter the bottle of Nursery® Water may also cause mold if not handled properly.

[Back to Top](#)

### **I thought babies couldn't be given fluoride. Can I give my baby Nursery® Water if it has fluoride?**

Nursery® Water has fluoride added in a concentration of up to 0.7 mg/L (a level that meets the concentrations recommended by the American Academy of Pediatrics). Consult with your Pediatrician or dental professional if you have questions.

[Back to Top](#)

### **If I use Nursery® Water do I still give my child fluoride supplements?**

Nursery® Water is NOT a fluoride supplement. Consult your physician if using other fluoridated products and consult your dental professional for appropriate oral hygiene practices.

[Back to Top](#)

### **The label says Nursery® Water is "sodium free", but the ingredients list "sodium fluoride." How can you say it is Sodium Free?**

Federal regulations allow products to be labeled as "sodium free" if the level of sodium is less than 5 milligrams per Liter in an 8 ounce serving. The level of sodium in Nursery® Water falls below this level.

[Back to Top](#)

### **Is Nursery® Water an electrolyte solution?**

Nursery® Water is a bottled water, and does NOT contain electrolytes and should never be used as a nutritional supplement.

[Back to Top](#)