# Acute Fluoride Toxicity from Ingesting Home-use Dental Products in Children, Birth to 6 Years of Age

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**Abstract**

***Objectives:*** *This paper analyzes reports to the American Association of Poison Control Centers (AAPCC) of suspected overingestion of fluoride by children younger than 6 years of age between 1989 and 1994, and estimates the probably toxic amounts of various home-use fluoride products in children younger than 6 years of age.* ***Methods:*** *Annual incidence rates of reported fluoride exposures attributed to dietary supplements, toothpaste, and rinses were calculated. Probably toxic amounts of each product were calculated using the frequently cited dose of 5 mg/kg.* ***Results:*** *Children younger than 6 years of age accounted for more than 80 percent of reports of suspected overingestion. While the outcomes were generally not serious, several hundred children were treated at health care facilities each year. A 10 kg child who ingests 50 mg fluoride (10.1 g 1.1% NaF gel; 32.7 g 0.63% $SnF_2$ gel; 33.3 g 1,500 ppm F toothpaste; 50 g 1,000 ppm F toothpaste; and 221 mL 0.05% NaF rinse) will have ingested a probably toxic dose.* ***Conclusions:*** *Overingestion of fluoride products in the home is preventable. Dentists and other health care providers should educate parents and child care providers about the importance of keeping fluoride products out of reach of children. Manufacturers should be encouraged by the ADA and the FDA to use child-resistant packaging for all fluoride products intended for use in the home. [J Public Health Dent 1997;57(3):150-8]*

*Key Words: fluoride, fluoride toothpaste, fluoride toxicity, fluoride mouthrinse, fluoride supplements, self-applied fluorides, fluoride gels.*

In 1994, the American Association of Poison Control Centers (AAPCC) recorded 10,596 calls about suspected overingestion of fluoride (reported exposures), approximately one-half percent of all reports to participating poison control centers (1). The exposures were attributed to dietary supplements (33.4%), toothpaste (31.5%), vitamins (23.5%), and mouthrinses (11.5%) (1).

The use of flavored consumer fluoride products increases the possibility that a child will ingest a toxic dose of fluoride. Acute fluoride toxicity can occur rapidly after the single ingestion of a large amount of fluoride. Soluble fluoride compounds, such as sodium fluoride, are rapidly and almost completely absorbed from the gastrointestinal tract (2). Recent studies also have found that most of the fluoride in ingested toothpaste is absorbed, although absorption can be delayed or reduced by the presence of food or milk (3-6). Blood plasma levels of fluoride generally peak within an hour of ingestion and excretion occurs almost exclusively in the urine (2,7,8).

Symptoms of acute fluoride toxicity vary depending on how much fluoride is ingested. At lower dosages, acute fluoride toxicity appears as nausea, upset stomach, and vomiting (9). As the amount of ingested fluoride increases, blood plasma levels also increase and the symptoms become severe and possibly life-threatening. Convulsions, tetany, and decreased myocardial contractility are associated with hypocalcemia caused by fluoride binding of circulating calcium. Hyperkalemia, also associated with toxic fluoride levels, can lead to ventricular arrhythmias and cardiac arrest. Death is usually the result of respiratory or cardiac failure.

Estimates of the lethal oral dose of sodium fluoride vary substantially. Based on a review of fluoride poisonings, Hodge and Smith (10) estimated that the certainly lethal dose (CLD) for adults ranged from 32 to 64 mg F/kg body weight. Within this range, every 70 kg adult would be expected to die. Whitford (11) reviewed several reports and concluded that more than 15 mg F/kg would likely be fatal for a small child.

Estimates of the probably toxic dose (PTD) also vary substantially. Whitford defines the PTD as "the minimum dose that could cause toxic signs and symptoms, including death, and that should trigger immediate therapeutic intervention and hospitalization" (11). From the findings of Hodge and Smith (10), Heifetz and Horowitz (9) concluded that a dose of 8 mg F/kg body weight could be safely tolerated. Bayless and Tinanoff (12) stated that oral doses of fluoride up to 5 mg F/kg generally produce mild gastrointestinal symptoms while doses of more than 5 mg F/kg could cause serious systemic toxicity. Whitford (11) reviewed reports by Eichler et al. (13), Dukes (14), and Bayless and Tinanoff (12), and concluded that the PTD of fluoride is 5 mg/kg body weight and that the different estimates of the toxic oral dose are largely due to "uncertainties about the quantities of fluorides ingested."

To reduce the likelihood of accidental poisoning among children, the American Dental Association (ADA) recommends that no more than 120 mg of elemental fluoride, or 264 mg of sodium fluoride, be dispensed in one container of fluoride rinse, nonabrasive gel, or dietary supplement. This 120-milligram maximum was based on an extrapolation of the data in the Hodge and Smith report (15). The

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American Dental Association Council on Dental Therapeutics used the average CLD for a 70 kg adult, 7.5 g of sodium fluoride, or 3,390 mg F. The estimated CLD for a 10 kg child is then 485 mg fluoride ion. The council decided that a child's life would not be endangered by one-quarter of the estimated lethal dose and established the 120 mg limit (15).

This paper reviews reports of suspected fluoride overingestion attributed to dietary supplements (with and without vitamins), toothpaste, and mouthrinses from 1989 to 1994. In addition to updating work done by Whitford (16), we estimate incidence rates adjusting for the lack of national poison control data and for the estimated number of households with children using the fluoride products. Finally, we estimate potential toxic doses of home-use fluoride products for children based on body weight.

## Methods

We considered dietary fluoride supplements with and without vitamins, and prescription and over-the-counter topical fluoride products in our analysis. Of the reported vitamin-fluoride combination exposures from 1989 to 1994, only the 16,290 (9.4%) of 173,527 reported exposures attributed to adult and pediatric multivitamins containing fluoride but no iron were included to avoid the possible confounding effects of iron toxicity. Vitamins without iron or fluoride, with iron and fluoride, and with iron but without fluoride comprised 33.4, 2.8, and 54.4 percent of multivitamin-related exposures, respectively (1,17-21).

Our data came from the annual summaries of the American Association of Poison Control Centers (AAPCC) published each September in the *American Journal of Emergency Medicine* (1,17-21). The AAPCC consolidates reports from participating local poison control centers that serve approximately 70 percent of the population (Table 1). Each local poison control center records the number of calls from individuals (e.g., parents, teachers, dentists, physicians, caregivers) asking for advice on dealing with possible overingestion.

**Estimation of Fluoride Doses.** We calculated the fluoride dose from ingesting 120 mg fluoride, the maximum amount of fluoride the ADA recommends be dispensed in one container, for children from 6 months to 6 years old using the 5th, 50th, and 95th percentiles of a standard growth and development table (22). The arithmetic average of boys' and girls' weights was determined for 6-month intervals between the ages of 6 months and 6 years. We then calculated the volume of mouthrinse in fluid ounces and the amount of toothpastes and gels in grams and ounces that would yield the probably toxic dose (PTD) of 5 mg/kg body weight when ingested. These calculations were done for several products at the 5th, 50th, and 95th percentiles of body weight. We also calculated the maximum amounts of mouthrinse (fluid ounces) and toothpastes and gels that would contain 120 mg fluoride, the ADA's recommended maximum.

**Calculation of Annual Incidence Rates.** The AAPCC records reports related to fluoride toothpastes and mouthrinses by age bands: younger than 6 years old, 6 to 17 years old, and older than 17 years and the proportion of the population covered by the AAPCC. We adjusted the frequencies for the entire US population for each year from 1989 to 1994 by dividing them by the proportion of the US

**TABLE 1**
**Coverage of American Association of Poison Control Centers: 1989–94***

| Year | Resident Pop. (Million) All Ages A | Resident Pop. (Million) <6 Years [A x .09] B | No. of Centers Reporting† C | % of Total Pop. Served D | Pop. Served (Million) [A x D] E | Pop. <6 Years Served [E x .09] F |
|---|---|---|---|---|---|---|
| 1989 | 246.8 | 22.2 | 70 | 73.9 | 182.4 | 16.4 |
| 1990 | 249.4 | 22.4 | 72 | 76.9 | 191.7 | 17.3 |
| 1991 | 252.2 | 22.7 | 73 | 79.6 | 200.7 | 18.1 |
| 1992 | 255.1 | 23.0 | 68 | 77.1 | 196.7 | 17.7 |
| 1993 | 257.6 | 23.2 | 64 | 70.4 | 181.3 | 16.3 |
| 1994 | 260.3 | 23.4 | 65 | 82.9 | 215.9 | 19.4 |

*Refs. 1, 17-21.
†Not all participating centers submitted data for the entire year.

**TABLE 2**
**Percent of Children (Birth to 17 Years of Age) Using Selected Fluoride-containing Dental Products: United States, 1983, 1986, 1989***

| Year | Age Band (Years) Dietary Supplement Birth–2 | Dietary Supplement 2–4 | Dietary Supplement 5–17 | Mouthrinse Birth–2 | Mouthrinse 2–4 | Mouthrinse 5–17 | Toothpaste Birth–2 | Toothpaste 2–4 | Toothpaste 5–17 |
|---|---|---|---|---|---|---|---|---|---|
| 1983 | 14.0 | 12.7 | 6.0 | 0.6 | 7.9 | 16.7 | 31.0 | 91.9 | 95.1 |
| 1986 | 16.3 | 14.4 | 6.2 | 1.2 | 9.4 | 19.2 | 33.4 | 91.2 | 93.7 |
| 1989 | 15.1 | 16.4 | 8.1 | 1.2 | 9.2 | 25.2 | — | — | — |

*Ref. 24.

**TABLE 3**
**Reports to the American Association of Poison Control Centers Related to Fluoride-containing Dental Products and the Outcomes, 1989–94***

| Year | Product | # Reports | # Treated in Health Care Facilities | Medical Outcome† | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | None | Minor | Moderate | Major | Death |
| 1989 | Toothpaste | 1,392 | 101 | 464 | 371 | 15 | 0 | 0 |
| | Mouthrinse | 1,185 | 56 | 503 | 115 | 3 | 0 | 0 |
| | Supplements | 4,028 | 375 | 1,807 | 663 | 14 | 1 | 1 |
| | Vitamins‡ | 3,153 | 184 | 1,214 | 135 | 0 | 0 | 0 |
| 1990 | Toothpaste | 1,379 | 107 | 468 | 329 | 7 | 0 | 0 |
| | Mouthrinse | 1,299 | 64 | 511 | 109 | 2 | 0 | 0 |
| | Supplements | 4,437 | 338 | 1,950 | 653 | 10 | 0 | 0 |
| | Vitamins‡ | 2,938 | 135 | 949 | 0 | 0 | 0 | 0 |
| 1991 | Toothpaste | 1,623 | 120 | 497 | 403 | 15 | 0 | 0 |
| | Mouthrinse | 1,418 | 72 | 556 | 112 | 0 | 0 | 0 |
| | Supplements | 4,350 | 368 | 1,593 | 667 | 12 | 1 | 0 |
| | Vitamins‡ | 2,741 | 102 | 595 | 93 | 3 | 0 | 0 |
| 1992 | Toothpaste | 2,331 | 141 | 700 | 497 | 17 | 1 | 0 |
| | Mouthrinse | 1,388 | 52 | 545 | 92 | 1 | 0 | 0 |
| | Supplements | 4,171 | 340 | 1,579 | 624 | 12 | 0 | 0 |
| | Vitamins‡ | 2,949 | 122 | 883 | 111 | 1 | 0 | 0 |
| 1993 | Toothpaste | 2,507 | 143 | 725 | 571 | 21 | 0 | 0 |
| | Mouthrinse | 1,144 | 52 | 409 | 75 | 4 | 0 | 0 |
| | Supplements | 3,483 | 249 | 1,143 | 503 | 16 | 0 | 1 |
| | Vitamins‡ | 2,650 | 105 | 706 | 100 | 0 | 0 | 0 |
| 1994 | Toothpaste | 3,339 | 166 | 852 | 800 | 19 | 1 | 0 |
| | Mouthrinse | 1,220 | 40 | 409 | 79 | 3 | 0 | 0 |
| | Supplements | 3,544 | 240 | 1,224 | 489 | 22 | 1 | 0 |
| | Vitamins‡ | 2,493 | 86 | 663 | 111 | 0 | 0 | 0 |

*Refs. 1, 17-21.
†*No effect:* No signs or symptoms as the result of exposure. *Minor effect:* Minimally bothersome signs or symptoms that generally resolved without residual disability or disfigurement (e.g., self-limiting gastrointestinal symptoms). *Moderate effect:* More pronounced or prolonged signs or symptoms, or more of a systemic nature than minor symptoms. While the symptoms are not life-threatening (e.g., disorientation or high fever that responds readily to treatment), some form of treatment is indicated. *Major effect:* Signs and symptoms that are life-threatening or result in significant residual disability or disfigurement.
‡With fluoride but without iron.

**TABLE 4**
**Reports to the American Association of Poison Control Centers Related to Oral Care Products Containing Fluoride and the Outcomes, 1992: Children under 6 Years of Age***

| Product | # Reports | # Treated in Health Care Facilities | Medical Outcome† | | | |
|---|---|---|---|---|---|---|
| | | | None | Minor | Moderate | Major |
| Toothpaste | 1,999 | 94 | 664 | 387 | 6 | 1 |
| Mouthrinse | 1,090 | 37 | 455 | 64 | 0 | 0 |
| Supplements | 3,788 | 268 | 1,505 | 519 | 8 | 0 |
| Vitamins‡ | 2,860 | 107 | 354 | 99 | 0 | 0 |

*Ref. 20.
†No deaths were reported.
‡With fluoride but without iron.

population participating in the AAPCC surveillance program each year (1,17-21). We then calculated an annual incidence rate using the adjusted number of reports as the numerator and the population of children younger than 6 years of age as the denominator (23). We focused on children younger than 6 years of age for two reasons: this age group accounted for 77 to 97 percent of the reported exposures and the AAPCC uses this age band to report its summary data.

We used data from the 1989 National Health Interview Survey (NHIS) to determine the number of children using various fluoride products to estimate incidences of reports of suspected fluoride overingestion of mouthrinses and dietary supplements (24). However, since children often ingest others' products, the best data would be the number of homes with children in which the products are used. This type of data is generally not available, so we used the NHIS data as a surrogate. Because the 1989 NHIS data were reported in age bands of younger than 2 years old, 2 to 4 years old, and 5 to 17 years old (Table 2) and our study focuses on children from birth to 6 years of age, we used census data (23) to extract the number of children younger than 6 years of age in the 5- to 17-year-old age band. We then computed a weighted average of the number of children younger than 6 years of age using fluoride mouthrinses (6%) and dietary supplements (15%). We used the proportion of the population using fluoride toothpaste (97%) to calculate incidences at all ages (25).

## Results

A review of AAPCC reports from 1989 to 1994 (Table 3) shows that while the outcomes were generally not serious, several hundred people of all ages each year were treated at health care facilities (1,17-21). Children younger

**TABLE 5**
**Reports to the American Association of Poison Control Centers Related to Fluoride Supplements: Children Younger than 6 Years of Age, 1989–94***

| Year | Unadjusted # of Reports A | Adjusted Reports to Represent Whole US Pop. B | Incidence (per 100,000) All Children < 6 C | # Children Using Supplements (Million)† D | Incidence (per 100,000) Children < 6 Using Supplements E |
|---|---|---|---|---|---|
| 1989 | 3,625 | 4,905 | 29.9 | 3.33 | 147.3 |
| 1990 | 3,915 | 5,091 | 29.6 | 3.36 | 151.5 |
| 1991 | 3,972 | 4,990 | 27.6 | 3.41 | 146.3 |
| 1992 | 3,778 | 4,900 | 27.7 | 3.45 | 142.0 |
| 1993 | 3,088 | 4,386 | 26.9 | 3.48 | 126.0 |
| 1994 | 3,159 | 3,810 | 19.6 | 3.51 | 108.5 |
| Mean | 3,590 | 4,680 | 26.9 | 3.42 | 136.9 |

*Refs. 1, 17-21.
†15 percent of children reported to use fluoride supplements (24).

**TABLE 6**
**Reports to the American Association of Poison Control Centers Related to Vitamins with Fluoride: Children Younger than 6 Years of Age, 1989–94***

| Year | Unadjusted # of Reports A | Adjusted Reports to Represent Whole US Pop. B | Incidence (per 100,000) All Children < 6 C | # Children Using Vitamins (Million)† D | Incidence (per 100,000) Children < 6 Using Supplements E |
|---|---|---|---|---|---|
| 1989 | 3,085 | 4,175 | 25.5 | 3.33 | 125.4 |
| 1990 | 2,852 | 3,709 | 22.6 | 3.36 | 110.4 |
| 1991 | 2,625 | 3,298 | 20.1 | 3.41 | 95.3 |
| 1992 | 2,860 | 3,710 | 22.6 | 3.45 | 107.5 |
| 1993 | 2,521 | 3,581 | 21.8 | 3.48 | 102.9 |
| 1994 | 2,393 | 2,887 | 17.6 | 3.51 | 81.5 |
| Mean | 2,723 | 3,560 | 21.7 | 3.42 | 102.8 |

*Refs. 1, 17-21.
†15 percent of children reported to use fluoride supplements (24).

**TABLE 7**
**Reports to the American Association of Poison Control Centers Related to Fluoride Toothpaste: Children Younger than Age 6 Years of Age, 1989–94***

| Year | Unadjusted # of Reports A | Adjusted Reports to Represent Whole US Pop. B | Incidence (per 100,000) All Children < 6 C | # Children with Fluoride Toothpaste in Home (Million)† D | Incidence (per 100,000) Children < 6 E |
|---|---|---|---|---|---|
| 1989 | 1,132 | 1,532 | 6.8 | 21.72 | 7.1 |
| 1990 | 1,119 | 1,456 | 6.5 | 21.94 | 6.6 |
| 1991 | 1,351 | 1,698 | 7.5 | 22.18 | 7.7 |
| 1992 | 2,011 | 2,608 | 11.3 | 22.45 | 11.6 |
| 1993 | 1,990 | 2,828 | 12.2 | 22.66 | 12.5 |
| 1994 | 2,566 | 3,095 | 13.2 | 22.87 | 13.5 |
| Mean | 1,695 | 2,203 | 9.6 | 22.30 | 9.8 |

*Refs. 1, 17-21.
†97 percent of children reported to use fluoride toothpaste (24).

**TABLE 8**
**Reports to the American Association of Poison Control Centers Related to Fluoride Mouthrinses: Children Younger than 6 Years of Age, 1989–94***

| Year | Unadjusted # of Reports A | Adjusted Reports to Represent Whole US Pop. B | Incidence (per 100,000) All Children < 6 C | # Children with FluorideMouthrinses (Million)† D | Incidence (per 100,000) Children < 6 Using Fluoride Mouthrinses E |
|---|---|---|---|---|---|
| 1989 | 868 | 1,175 | 5.3 | 1.34 | 87.7 |
| 1990 | 1,109 | 1,316 | 5.9 | 1.36 | 96.8 |
| 1991 | 1,105 | 1,384 | 6.1 | 1.37 | 101.0 |
| 1992 | 1,094 | 1,419 | 6.2 | 1.39 | 102.1 |
| 1993 | 888 | 1,262 | 5.4 | 1.39 | 90.8 |
| 1994 | 924 | 1,115 | 4.8 | 1.40 | 79.6 |
| Mean | 998 | 1,279 | 5.6 | 1.38 | 93.0 |

*Refs. 1-6.
†6 percent of children reported to use fluoride mouthrinses (24).

than 6 years of age accounted for 97, 81, 79, and 77 percent of reported exposures to fluoride-vitamin combinations, fluoride toothpaste, supplements, and mouthrinses, respectively. Between 1989 and 1994, fluoride-related exposures in children younger than 6 years of age attributed to fluoride toothpaste and mouthrinse increased from 1,392 to 3,339 (140%) and 1,185 to 1,220 (3.0%), respectively. Those attributed to fluoride vitamins decreased from 3,153 to 2,493 (20.9%), while dietary fluoride supplements decreased from 4,028 to 3,544 (12.0%).

The AAPCC provided a breakdown of outcomes of reported exposures for children younger than 6 years of age for 1992 only (20). Table 4 shows there were no fatalities, only one outcome categorized as major (life-threatening, resulting in residual disability), 14 (0.14%) as moderate (pronounced and prolonged signs and symptoms with treatment indicated), 1,069 (10.9%) as minor (some signs and symptoms that resolve rapidly), and 2,978 (30.6%) with no symptomatology on follow-up. Five-hundred and six (5.2%) children younger than 6 years of age were treated at health care facilities in 1992.

Table 1 shows the US resident population, the population younger than 6 years of age, the number of poison control centers participating in the AAPCC surveillance program, the proportion of the resident population participating in the AAPCC surveillance program, and the population served by the poison control centers. We used the percentage of children younger than 6 years of age in 1991 (9%) to calculate population younger than 6 years of age served (column F). In Tables 5–8, column A shows reports to the AAPCC attributed to fluoride supplements without and with vitamins, fluoride toothpaste, and fluoride mouthrinse, respectively, among children younger than 6 years of age; column B, the adjusted number of reports among children younger than 6 years of age for the entire US population; column C, the incidence per 100,000 children younger than 6 years of age; column D, the estimated number of children exposed to each

**TABLE 9**
**Fluoride Dose from Ingesting 120 Milligrams Fluoride: Children Aged 6 Months to 6 Years***

| | 5th Percentile Body Weight | | 50th Percentile Body Weight | | 95th Percentile Body Weight | |
|---|---|---|---|---|---|---|
| Age (Years) | Weight (kg)* | Dose (mg/kg) from Ingesting 120 mg F | Weight (kg)* | Dose (mg/kg) from Ingesting 120 mg F | Weight (kg)* | Dose (mg/kg) from Ingesting 120 mg F |
| 0.5 | 6.00 | 20.0 | 7.53 | 15.9 | 9.10 | 13.2 |
| 1.0 | 8.14 | 14.7 | 10.15 | 11.8 | 11.62 | 10.3 |
| 1.5 | 9.59 | 12.5 | 11.47 | 10.5 | 13.10 | 9.2 |
| 2.0 | 10.54 | 11.4 | 12.59 | 9.5 | 14.39 | 8.3 |
| 2.5 | 11.44 | 10.5 | 13.67 | 8.8 | 15.66 | 7.7 |
| 3.0 | 12.26 | 9.8 | 14.69 | 8.2 | 16.91 | 7.1 |
| 3.5 | 12.84 | 9.3 | 15.68 | 7.7 | 18.78 | 6.4 |
| 4.0 | 13.64 | 8.8 | 16.69 | 7.2 | 20.09 | 6.0 |
| 4.5 | 14.45 | 8.3 | 17.69 | 6.8 | 21.44 | 5.6 |
| 5.0 | 15.27 | 7.9 | 18.67 | 6.4 | 22.86 | 5.2 |
| 5.5 | 16.09 | 7.5 | 19.67 | 6.1 | 24.39 | 4.9 |
| 6.0 | 16.93 | 7.1 | 20.69 | 5.8 | 26.05 | 4.6 |

*Ref. 22.

fluoride-containing home-use product; and column E, the incidence per 100,000 children presumed to have the products in their home.

The annual incidence of reported exposures attributed to fluoride supplements (Table 5) and vitamins with fluoride (Table 6) showed slight declines from 1989 to 1994, with six-year means of 26.9 and 21.7 exposures per 100,000 children younger than 6 years of age (column C) for dietary supplements and vitamins, respectively.

The number of reports, adjusted to represent the whole US population, relating to fluoride-containing toothpaste ranged from 1,456 in 1990 to 3,095 in 1994, with a six-year mean of 2,203 (Table 7, column B). Annual incidences among all children younger than 6 years of age ranged from 6.5 to 13.2 per 100,000 (column C), with a six-year mean of 9.6 reported exposures. The incidence among children presumed to have fluoride toothpaste in the home (column E) was only slightly greater because fluoride-containing toothpaste is used so widely.

Table 8 shows that adjusted reported exposures relating to fluoride mouthrinses (column B) ranged from 1,115 to 1,419, with a six-year mean of 1,279. Annual incidences ranged from 4.8 to 6.2 per 100,000 children with a six-year mean of 5.6 (column C), while that among children reported to use mouthrinses ranged from 79.6 to 102.1 per 100,000 with a six-year mean of 93.0 (column E).

**TABLE 10**
**Concentration of Fluoride in Topical Home Use Products***

| | Fluoride Concentration | | Amount Containing | Largest Size Available | |
|---|---|---|---|---|---|
| Product | ppm# | mg/oz | 120 mg F (g)** | Size (oz) | F Content (mg) |
| 0.05% NaF rinse | 230 | 6.51 | 522.00 | 18.00 | 117.2 |
| 0.20% NaF rinse† | 920 | 26.04 | 132.00 | 16.00 | 417.0 |
| 0.4% $SnF_2$ gel‡ | 970 | 27.45 | 124.00 | 4.30 | 118.0 |
| Toothpaste¶ | 1,000 | 28.35 | 120.00 | 8.20 | 232.0 |
| Toothpaste§ | 1,500 | 42.45 | 80.00 | 6.00 | 254.7 |
| 0.63% $SnF_2$ gel+ | 1,528 | 43.24 | 79.00 | 2.50 | 108.0 |
| 1.1% NaF gel• | 4,950 | 140.08 | 24.00 | 2.00 | 280.0 |

*Shaded rows indicate products that exceed 120 mg fluoride in largest container.
†For example, Fluorinse®, Point-Two, NaFrinse.
‡For example, Control, Easy-Gel, Flocare, Gel-Kam, Stop-Gel, Stan-Gard, Gel-Tin.
¶For example, Aim, Aquafresh, Close-Up, Colgate, Macleans, Viadent with Fluoride.
§For example, Extra Strength Aim.
+For example, GelKam Oral Care Rinse, Perio-Med.
•For example, Neutracare™, Prevident, Karigel-N, Thera-Flur-N.
#The density of mouthrinse is approximately 1.00 (1.00 g/1.00 mL), so 522 g 0.05 percent mouthrinse has a volume of 522 mL.
**ppm=mg F/kg of product.

Table 9 shows 5th, 50th, and 95th percentile average body weights of boys and girls at six-month intervals between 6 months and 6 years of age, and the dose (mg/kg) from ingesting 120 mg fluoride, the ADA-recommended maximum amount of fluoride that should be dispensed to a patient (17). The highest dose (20.0 mg F/kg) is in a 6-month-old at the 5th percentile. There is approximately a 20 percentage point difference between body weight at each of the 5th versus 50th and 50th versus 95th percentiles; consequently, doses for children at the 5th percentile are approximately 20

percentage points higher than those at the 50th percentile while those for children at the 95th percentile are 20 percentage points lower. Virtually all doses exceed the PTD of 5 mg/kg.

Table 10 shows the concentration of fluoride in topically applied home-use products, the amount of a product that contains 120 mg fluoride, and the largest size available to consumers. Fluoride concentrations range from 230 ppm for 0.05 percent NaF rinse to 4,950 ppm for 1.1 percent NaF gel. Several products, indicated by shaded cells, are sold with more fluoride than the ADA-recommended 120 mg per container ceiling.

Figure 1 shows the quantity of ingested toothpaste that contains the probably toxic dose in children at the 5th, 50th, and 95th percentiles. For example, the PTD of 1,000 ppm toothpaste for a 1-year-old child at the 5th percentile is [(8.14 kg x 5 mg F/kg) ÷28.35 mg F/oz], or 1.44 ounces; at the 50th percentile, the PTD is [(10.15 kg x 5 mg F/kg) ÷ 28.35 g F/oz], or 1.79 ounces. The PTD for 1,500 ppm toothpaste is one-third lower.

Figure 2 shows the PTD for an over-the-counter daily rinse and a prescription weekly rinse. For a child at the 5th percentile, PTDs of 0.20 percent NaF ranged from 1.56 (fluid) ounces for a 1-year-old to 3.25 ounces for a 6-year-old. For a child at the 50th percentile, the PTD for a 6-year-old is 3.97 fluid ounces. PTDs for children ingesting 0.05 percent NaF rinses are four times higher than those of 0.20 percent NaF.

Figure 3 shows the PTD of two fluoride gels, 0.40% $SnF_2$ and 1.1% NaF. At the 5th percentile, the PTDs of 1.10% NaF gel range from 0.29 ounces at age 1 year to 0.60 ounces at age 6 years. At the 50th percentile, PTDs range from 0.36 ounces at age 1 year to 0.74 ounces at 6 years of age. For a child at the 5th percentile, PTDs of 0.40% $SnF_2$ gel range from 1.48 to 3.08 ounces, while at the 50th percentile, PTDs range from 1.85 to 3.77 ounces.

## Discussion

The ADA recommends that no more than 120 mg of fluoride be prescribed to a patient (15). But the 120-milligram limit was set to prevent fatalities or a severe toxic reaction, not to prevent mild to moderate toxicity. Table 9 shows that a 1-year-old child at the 5th percentile of body weight (8.14 kg) who ingests 120 mg of fluoride

FIGURE 1
**Quantity of Ingested Toothpaste Containing Probably Toxic Dose (5 mg F/kg Body Weight) at 5th, 50th, and 95th Percentiles of Body Weight in Children 6 Months to 6 Years of Age**

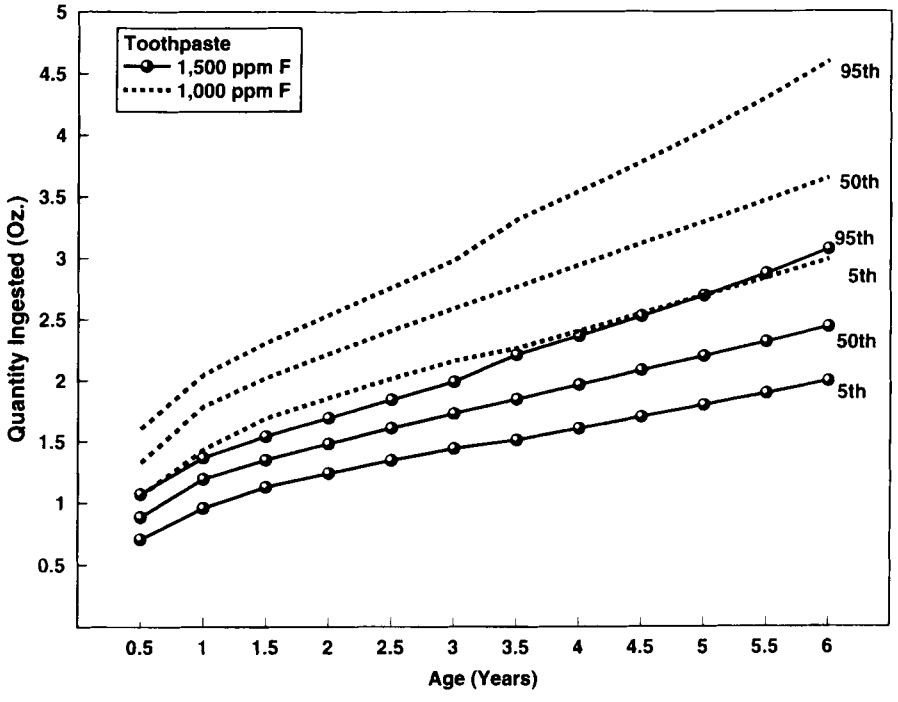



FIGURE 2
**Quantity of Ingested Mouthrinse Containing Probably Toxic Dose (5 mg F/kg Body Weight) at 5th, 50th, and 95th Percentiles of Body Weight in Children 6 Months to 6 Years of Age**

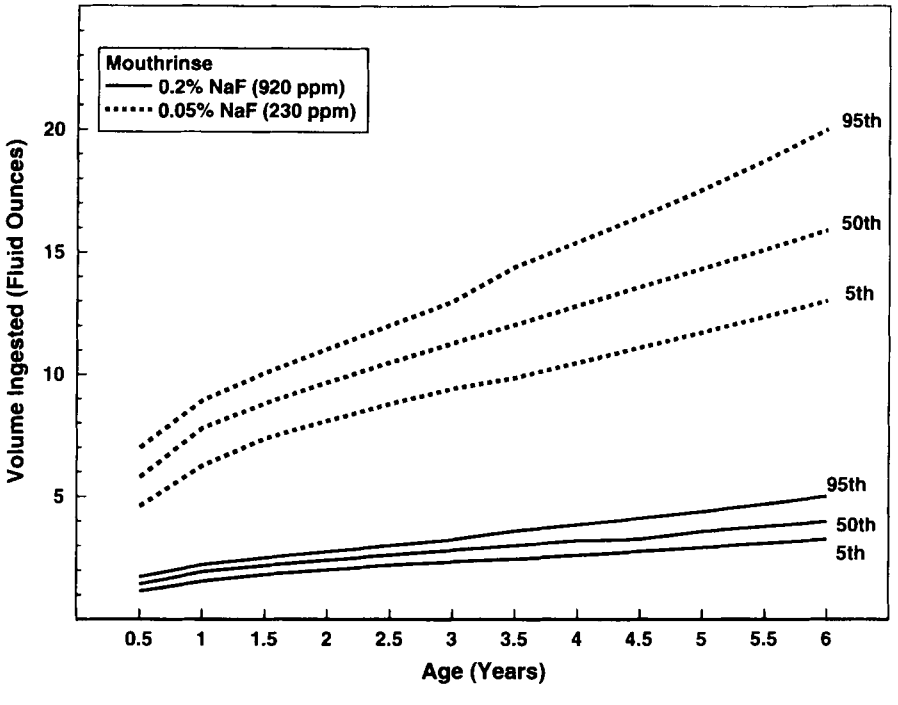
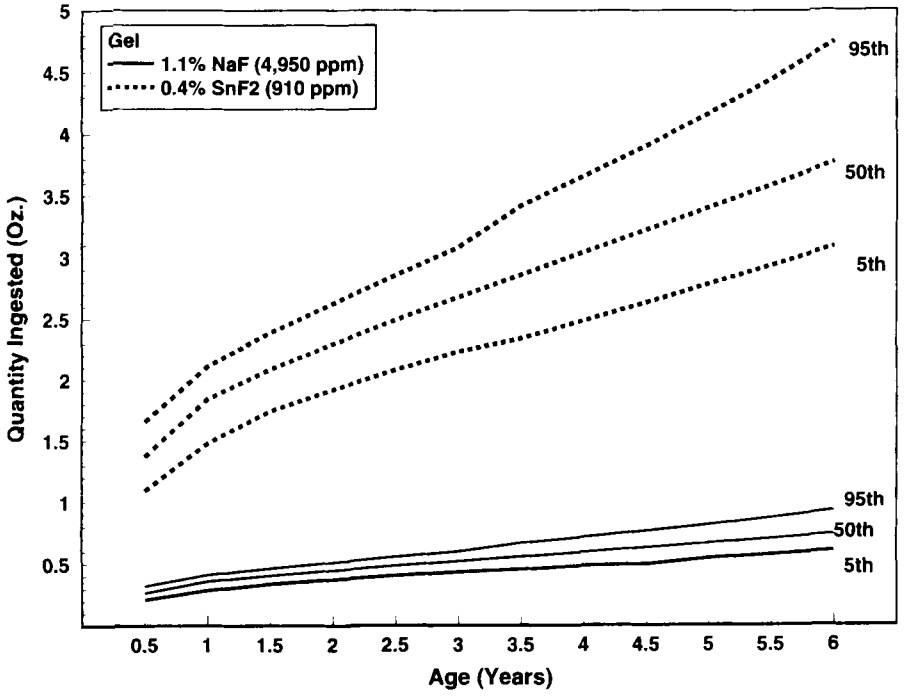


FIGURE 3
**Quantity of Ingested Self-applied Gel Containing Probably Toxic Dose (5 mg F/kg Body Weight) at 5th, 50th, and 95th Percentiles of Body Weight in Children 6 Months to 6 Years of Age**




takes in 14.7 mg/kg, almost three times the PTD suggested by Whitford (15). While this is an extreme example, the dosage rate for a 3-year-old child at the 50th percentile (14.69 kg) would still be 8.2 mg/kg, almost 70 percent higher than the presumptive PTD. Our data show that especially in young children ingesting relatively small volumes of home-use products can reach the PTD. Ingestion of less than 1 ounce of the product with the highest fluoride concentration we examined and less than 2 ounces of many other products can reach a PTD.

The ADA recommendation, however, does not apply to over-the-counter products such as dentifrices, mouthrinses, and some gels, although—as shown in Table 10—some of these products contain more than 120 mg of fluoride. A 6 oz container of 1,500 ppm fluoride toothpaste contains 254.7 mg of fluoride. A 1-year-old (8.14 kg) child ingesting less than one-fifth of the contents of the container would exceed the PTD.

Estimating the incidence of acute fluoride toxicity is difficult for a variety of reasons. In many cases, children in households that do not use a particular fluoride-containing product will have little or no access to that product, reducing the likelihood of poison exposures. To account for this possibility, we adjusted the incidence of reported fluoride exposures for the proportion of children under age 6 who use fluoride-containing toothpastes, mouthrinses, and supplements (24). The effect of this adjustment is to reduce the size of the denominator and increase the estimated incidence.

There are two problems with this approach. First, the NHIS data are 7 years old and the proportion of children using the products may have changed. Table 2 shows trends in the use of fluoride-containing products by school-aged children reported in national surveys performed in 1983, 1986, and 1989 (24). Use of fluoride supplements and mouthrinses increased substantially, while fluoride toothpaste use was essentially unchanged (24). To the extent that the NHIS understates (or overstates) the number of children currently using the products, the estimated annual incidences will be too high (or too low). Second, the NHIS reported the number of children using the fluoride products, not number of households in which the products are used. Since children may have access to parents' or siblings' products, the number of children exposed will be understated and the estimated incidences will be too high.

Estimating the incidence of toxic fluoride exposures nationwide also is complicated by the existence of biases. Parents or caregivers may not notice the symptoms associated with mild fluoride toxicity or may attribute them to colic or gastroenteritis, particularly if they did not see the child ingest fluoride. Similarly, because of the nonspecific nature of mild to moderate symptoms, a physician's differential diagnosis is unlikely to include fluoride toxicity without a history of fluoride ingestion. Parents and caregivers may not report a suspected overingestion because they are unaware of the existence of a local poison control center or they may choose not to report it. Finally, the number of exposures identified, by either parent or physician, and not reported is unknown since the symptoms are usually mild and often do not require treatment in a health care facility. These biases will result in an underestimate of the incidence of acute fluoride toxicity.

Besides the biases that would lead to underreporting, several would result in overstating the incidence of reported fluoride toxicity. In a child with a history of ingesting a fluoride-containing product, a parent, caregiver, or physician may erroneously attribute the symptoms of nausea and vomiting to fluoride toxicity. Also, sometimes a parent may report that a child ingested fluoride, but the unknown small amount ingested would not cause any symptoms.

While we recognize that biases are operating in both directions, we feel there is substantial underreporting due to a general lack of awareness among parents, physicians and even dentists for a potentially acute toxic reaction to fluoride. Consequently, we believe that the incidence of acute fluoride toxicity is underestimated.

Overingestion of fluoride products in the home is preventable. Parents should be aware of the potential toxicity of fluoride-containing products in their home and take precautions to prevent accidental ingestion such as keeping the products out of the reach of children, supervising children while the products are being used, and purchasing products with child-resistant packaging when possible. Dentists should educate parents,

caregivers, and other health care providers about acute fluoride toxicity—the cause, symptoms, and treatment.

The ADA should extend its recommendation of not dispensing more than 120 mg elemental fluoride at one time to nonprescription fluoride products as a condition of receiving its seal of approval. Given recent studies that found almost total absorption of the fluoride in dentifrices (7-10), the recommended fluoride limit also should include dentifrices. Further, the ADA should consider lowering the 120 mg limit. In the current literature, 5 mg/kg, not 12 mg/kg, is the "accepted" probably toxic dose that could require intervention. Finally, the FDA should require manufacturers to adhere to the 120 mg limit or to offer child-resistant caps on their products. While these changes could result in a small increase in cost to the manufacturer (which might be passed on to the consumer), we feel that the cost of these measures is outweighed by the additional protection provided to children.

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