Children's Hospital of Philadelphia

Vaccine Ingredients - Aluminum

Aluminum is the third most abundant element after oxygen and silicon, and it is the most abundant metal, making up almost 9 percent of the earth's crust. Aluminum is found in plants, soil, water and air. Most plants have low quantities of aluminum, but a few are known to be aluminum accumulators, including some types of tea plants, grasses and orchids.

Aluminum is used extensively in various ways:

- Aluminum can be found in food-related products including pots and pans; storage containers, such as beverage cans; and foil.
- Aluminum is found in numerous foods and beverages including fruits and vegetables, beer and wine, seasonings, flour, cereals, nuts, dairy products, baby formulas, and honey. Typically, adults ingest 7 to 9 milligrams of aluminum per day.
- Aluminum is used for manufacturing of airplanes, siding, roofing materials, paints, pigments, fuels and cigarette filters.
- Aluminum is found in health products including antacids, buffered aspirin, antiperspirants and some vaccines.

Aluminum in vaccines

Aluminum is used in vaccines as an adjuvant. An adjuvant is vaccine component that boosts the immune response to the vaccine. Adjuvants allow for lesser quantities of the vaccine and fewer doses. The adjuvant effects of aluminum were discovered in 1926. Aluminum adjuvants are used in vaccines such as hepatitis A, hepatitis B, diphtheria-tetanus-containing vaccines, *Haemophilus influenzae type* b, and pneumococcal vaccines, but they are not used in the live, viral vaccines, such as measles, mumps, rubella, varicella and rotavirus.

Vaccines containing adjuvants are tested extensively in clinical trials before being licensed. Aluminum salts, monophosphoryl A (a detoxified bacterial component), and squalene (a compound of the body's normal cholesterol synthesis pathway) are the only materials that can

be used as adjuvants in the United States. The quantities of aluminum present in vaccines are low and are regulated by the Center for Biologics Evaluation and Research (CBER).

The aluminum contained in vaccines is similar to that found in a liter (about 1 quart or 32 fluid ounces) of infant formula. While infants receive about 4.4 milligrams* of aluminum in the first six months of life from vaccines, they receive more than that in their diet. Breast-fed infants ingest about 7 milligrams, formula-fed infants ingest about 38 milligrams, and infants who are fed soy formula ingest almost 117 milligrams of aluminum during the first six months of life.

***Note**: One milligram is one-thousandth of a gram. One gram is the weight of one-fifth of a teaspoon of water.

For more information about ingestion versus injection of aluminum, please review our Q&A sheet (English, Spanish, and Japanese) and this video.

Quantities of aluminum in vaccines

Pneumococcal vaccine

- 0.125 milligram per dose (mg/dose)

Diphtheria-tetanus-acellular pertussis (DTaP) vaccine

- < 0.33 to < 0.625 mg/dose

Haemophilus influenzae type b (Hib) vaccine

- 0.225 mg/dose

Hepatitis A vaccine (Hep A)

- 0.225 to 0.25 mg/dose (pediatrics)
- 0.45 to 0.5 mg/dose (adults)

Hepatitis B vaccine (Hep B)

- 0.225 to 0.5 mg/dose (pediatrics)
- 0.5 mg/dose (adults)

Hep A/Hep B vaccine

- 0.45 mg/dose

DTaP/inactivated polio/Hep B vaccine

- < 0.85 mg/dose

DTaP/inactivated polio/Hib vaccine

- 0.33 mg/dose

Human Papillomavirus (HPV) vaccine

- 0.5 mg/dose

Japanese Encephalitis (JE) vaccine

- 0.25 mg/dose

Meningococcal B vaccine

- 0.25 – 0.52 mg/dose

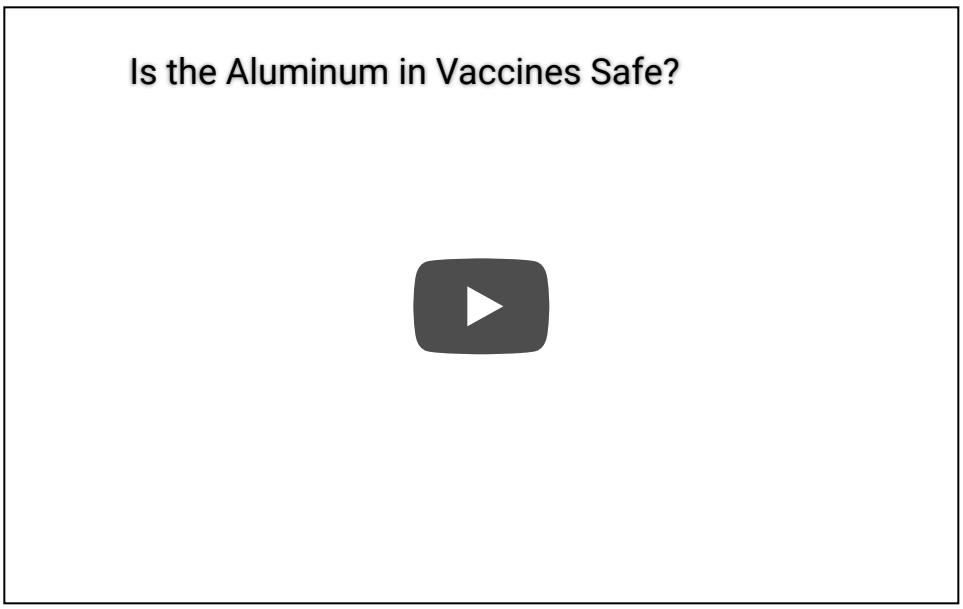
Td vaccine

- < 0.53 – 1.5 mg/dose

Tdap vaccine

- 0.33 – 0.39 mg/dose

"Is the Aluminum in vaccines safe?"



View this video with a transcript

"Is There a Difference Between Aluminum That Is Injected vs. Ingested?"

View this video with a transcript

Aluminum in other substances

Quantities of aluminum in other substances

Breast milk

- 0.04 milligrams per liter (mg/L)

Ponds, lakes, streams

- 0.1 mg/L

Infant formula

- 0.225 mg/L

Soy-based formula

- 0.46 to 0.93 mg/L

Buffered aspirin

- 10 to 20 mg/tablet

Antacid

- 104-208 mg/tablet

Given the quantities of aluminum we are exposed to on a daily basis, the quantity of aluminum in vaccines is miniscule. Aluminum-containing vaccines have been used for decades and have been given to more than 1 billion people without problem. In spring 2000, the National Vaccine Program Office (NVPO) reviewed aluminum exposure through vaccines and determined that no changes to vaccine recommendations were needed based on aluminum content. The Global Advisory Committee on Vaccine Safety, part of the World Health Organization (WHO), has also reviewed studies and found no evidence of health risks that would require changes to vaccine policy.

Health effects of aluminum

The health effects of aluminum have been studied; however, few have been shown to result from aluminum exposure. Kidney dialysis patients have developed disorders of the brain and bones due to the aluminum content in intravenous fluids and antacids following years of dialysis. Both disorders have decreased in occurrence due to improvements to dialysis systems. The bone disease was due to poor absorption of phosphate in the presence of high quantities of aluminum. Children taking large amounts of aluminum-based medications have also been found to suffer from this bone disorder.

It has been suggested that some diseases involving the brain, such as Alzheimer's disease, are caused by aluminum accumulation in brain tissues. However, studies have not consistently found increased levels of aluminum leading some to hypothesize that the aluminum accumulation may be the result of tissue damage rather than the cause of disease.

References

Karwowski MP, Stamoulis C, Wenren LM, et al. Blood and hair aluminum levels, vaccine history, and early infant development: a cross-sectional study**. Acad Pediatr 2018;18:161-**

165.
Children aged 9 to 13 months, excluding those who received aluminum-containing pharmaceuticals, were evaluated for blood and hair aluminum levels, vaccination history, and cognitive, language and motor development scores. The authors found no correlation between infant blood or hair aluminum concentrations and vaccine history or between blood aluminum and overall developmental status.

Ameratunga R, Gills D, Gold M, et al. Evidence refuting the existence of autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA)**. J Allergy Clin Immunol Pract 2017;5:1551-1555.**
The authors identified two studies refuting the claim for autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA) as suggested by Shoenfeld and coworkers. In one study, lupus patients were found to have no increase in exacerbations after receiving a hepatitis B vaccine containing an aluminum adjuvant. A second study evaluated the incidence of autoimmune disease in more than 18,000 patients who received subcutaneous allergen-specific immunotherapy containing large quantities of injected aluminum. Patients receiving injected aluminum were found to have a lower incidence of autoimmune disease compared with controls. The authors concluded that current studies do not support the existence of ASIA.

Mitkus RJ, King DB, Hess MA, et al. Updated aluminum pharmacokinetics following infant exposures through diet and vaccination**. Vaccine 2011; 29:9538-9543.**
The authors found that the burden of aluminum from diet and from vaccines given according to the CDC schedule within the first year of life was well within levels considered to be safe, even when the infant was small for age (i.e., equal to or less than the 5^{th}percentile for weight).

Jefferson T, Rudin M, Di Pietrantonj C. Adverse events after immunization with aluminium-containing DTP vaccines: systematic review of the evidence**. Lancet Infect Dis 2004;4:84-90**. The authors reviewed the incidence of adverse events after exposure to aluminum-containing diphtheria, tetanus and pertussis (DTP), alone or in combination, compared with identical vaccines, either without aluminum or containing aluminum in different concentrations. In children up to 18 months of age, aluminum-containing vaccines were associated with more erythema and induration than vaccines without aluminum. They were not, however, associated with serious adverse events.

Keith LS, Jones DE, Chou CHSJ. Aluminum toxicokinetics regarding infant diet and vaccinations**. Vaccine 2002;20:S13-S17.**
The authors determined whether exposure to aluminum in the diet and in vaccines during the

first year of life exceeded the minimal risk level (MRL) set by the Agency for Toxic Substances and Disease Registry (ATSDR). They found that the amount of aluminum received from vaccines was greater than that from dietary sources; however, this level was routinely below the MRL with the exception of brief periods immediately following vaccination. Levels of exposure slightly above the MRL were also likely to be safe given the manner in which the MRL is calculated.

Reviewed by Paul A. Offit, MD, Heather Monk Bodenstab, PharmD on March 22, 2018

Language Assistance Available: