



Common Questions about

Vaccine Ingredients

Do vaccines contain harmful toxic substances?

Every vaccine undergoes safety testing before it is released, and manufacturers are required to list the contents of the vaccine for the Food and Drug Administration (FDA).

- In addition to the dead or weakened germ (or other purified components that are included in vaccines because they stimulate the immune system), vaccines usually contain sterile water or saline.
- Some vaccines are prepared with a preservative or antibiotic (to prevent bacterial growth).
- Some vaccines also are prepared with substances known as stabilizers (to help the vaccine maintain its effectiveness during storage).
- Another component of some vaccines is an adjuvant, such as aluminum (to help stimulate the production of antibodies against the vaccine and make it more effective).

Under strict supervision of the FDA, vaccines are tested by pharmaceutical companies throughout the development and manufacturing process and after the vaccine is licensed and made available for use. The FDA inspects the factory where the vaccine is produced to be sure that the vaccine is made in a safe and consistent manner. Each batch of vaccine is tested for purity, potency, and safety before it is given to children. A sample from each lot is sent to the FDA. In addition, the FDA sets limits on how much of a component, such as aluminum or thimerosal, may be included in a vaccine.

In 1999, a preservative known as thimerosal received attention because it contains mercury. As a part of a larger effort to examine environmental exposure to mercury, an FDA audit determined that while no individual vaccine contains more mercury (as part of the preservative thimerosal) than recommended, when considered together, some children might receive an amount of mercury that exceeds the guidelines of one federal agency Environmental Protection Agency (EPA) but not others (FDA and CDC). Each of the federal agency guidelines for mercury exposure have a generous safety margin (meaning that the levels they specify are far lower than the amount of mercury that actually would pose a health risk). To ensure the safety of vaccines, however, the U.S. Public Health Service and the American Academy of Pediatrics recommended reducing or eliminating the use of thimerosal-containing vaccines.^{1,2}

Although all exposures to mercury should be minimized, there is no evidence that any child has been harmed by exposure to the amounts of mercury in vaccines. In addition, the risk of disease from not immunizing a child is greater than the risk of exposure to low levels of mercury in thimerosal-containing vaccines. Therefore, children should be protected by immunization. For each recommended childhood vaccine, at least one thimerosal-free formulation is currently available. The FDA is working with each of the vaccine manufacturers to reduce thimerosal in vaccines without compromising their current safety and effectiveness.

Vaccine Ingredients(continued)

Are vaccines made from animal tissue safe? Can they transmit infectious agents to people?

Tests in the vaccine production process are used to ensure that vaccines are free from contamination by viruses, bacteria, fungi, and parasites and are screened for known infections of humans and animals. Millions of doses of vaccines have been given to children and adults without transmitting animal diseases.

- One recently reviewed situation from the past has to do with the polio vaccine. Polio vaccine is made by growing the virus in monkey kidney cells. The early batches of polio vaccine (used between 1955 and 1963) were contaminated with a virus that infects monkeys, simian virus 40 (SV40).^{3,5} The long-term follow-up studies conducted to date have not shown that those exposed to SV40-contaminated vaccine are at any additional risk of cancer, but scientific research is continuing. *The polio vaccines in use today are not contaminated.*
- Animals used for vaccine research now must be confined to sterile environments where they will not be exposed to viruses. In addition, vaccines are rigorously inspected for contamination. The Code of Federal Regulations (Title 9: Animal and Animal Products, Volume 1, Part 113) stipulates the requirements for production of vaccines and for testing their safety, purity, and virus identity.⁶ Standard requirements for cells and cell lines used to make live virus vaccines are provided in Parts 113.51 (primary cells), 113.52 (cell lines), and 113.53 (ingredients of animal origin).

Sources:

- 1 Halsey NA. Limiting infant exposure to thimerosal in vaccines and other sources of mercury. *JAMA* 1999;282:1763-1766.
- 2 American Academy of Pediatrics. Thimerosal in vaccines—An interim report to clinicians. *Pediatrics* 1999;104:570-574.
- 3 Rizzo P, Di Resta I, Powers A, Ratner H, Carbone M. Unique strains of SV40 in commercial polio vaccines from 1955 readily identifiable with current testing for SV40 infection. *Cancer Res* 1999;59:6103-6108.
- 4 Fisher SG, Weber L, Carbone M. Cancer risk associated with simian virus 40 contaminated polio vaccine. *Anticancer Res* 1999;19(3B):2173-2180.
- 5 Kuska B. SV40 bugaboo: spinning the news. *J Natl Cancer Inst* 1999;91:662-664.
- 6 Code of Federal Regulations (Title 9, Volume 1, Part 113). The Code of Federal Regulations may be accessed on the Internet at www.access.gpo.gov/nara/cfr/index.html#page1.

Recommended books and Web sites on this topic:

Humiston SG and Good C. *Vaccinating your child: Questions & answers for the concerned parent.* Atlanta: Peachtree Publishers; 2000.

Offit PA and Bell LM. *Vaccines: What every parent should know, revised edition.* New York: IDG Books; 1999.

American Academy of Pediatrics Web site (www.aap.org).

Centers for Disease Control and Prevention, National Immunization Program Web site (www.cdc.gov/nip).