



Common Questions about **Vaccine Ingredients**

What are vaccines made of? Are any of the ingredients in vaccines harmful?

- Vaccines can be developed in four different ways by using:
 - ▶ Live bacteria or viruses that have been altered so that they cannot cause disease
 - ▶ Killed bacteria or inactivated viruses
 - ▶ Toxoids (bacterial toxins that have been made harmless)
 - ▶ Purified parts of bacteria or viruses
- Vaccines usually contain sterile water or saline, as well as the dead or weakened germ and other purified components that are included in vaccines because they stimulate the immune system.
- Some vaccines are prepared with a preservative or antibiotic (to prevent bacterial and fungal 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 ingredients to make it more effective).

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).

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 or adults. A sample from each lot is sent to the FDA. In addition, the FDA sets limits on how much of a component, such as an adjuvant or preservative, may be included in a vaccine.

Concerns have been raised about the theoretical risk of harm from thimerosal, a preservative that contains mercury that has been used in small amounts in some vaccines for nearly 70 years. However, there is no evidence that any child has been harmed by exposure to the amounts of thimerosal in vaccines.¹⁻³ Recent changes in manufacturing techniques have allowed all routinely recommended childhood vaccines to be produced free of thimerosal or with only trace amounts.⁴ Some vaccines, including all live-virus vaccines, never contained thimerosal.

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 organisms causing 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. When a virus that affects monkeys now known as simian virus 40 (SV40) was identified, researchers were able to test earlier batches of polio vaccines and found that some early batches (used between 1955 and 1963) were contaminated with that virus.⁵⁻⁷ Because the virus was found to cause tumors in some laboratory animals, some speculated that its presence in polio vaccine might result in some types of cancer in humans. The long-term follow-up studies conducted to date have not shown that those exposed to vaccine contaminated with SV40 are at any additional risk of cancer, but scientific research is continuing.⁸⁻¹⁰ *The polio vaccines in use today are tested to be sure that they do not contain SV40.*
- 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.¹¹ 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 Institute of Medicine. (2001). *Immunization safety review: Thimerosal-containing vaccines and neurodevelopmental disorders*. Washington, DC: National Academy Press. Available online: www.iom.edu/IOM/IOMHome.nsf/Pages/thimerosal+report
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- 3 Halsey NA. (1999). Limiting infant exposure to thimerosal in vaccines and other sources of mercury. *Journal of the American Medical Association*, 282(18), 1763-1766.
- 4 American Academy of Pediatrics, Committee on Infectious Diseases and Committee on Environmental Health. (1999). Thimerosal in vaccines—An interim report to clinicians. *Pediatrics*, 104(3 Pt 1), 570-574.
- 5 Rizzo P, Di Resta I, Powers A, Ratner H, and Carbone M. (1999). Unique strains of SV40 in commercial polio vaccines from 1955 readily identifiable with current testing for SV40 infection. *Cancer Research*, 59, 6103-6108.
- 6 Fisher SG, Weber L, and Carbone M. (1999). Cancer risk associated with simian virus 40 contaminated polio vaccine. *Anticancer Research*, 19(3B), 2173-2180.
- 7 Kuska B. SV40 bugaboo: Spinning the news. (1999). *Journal of the National Cancer Institute*, 91(8), 662-664.
- 8 Carroll-Pankhurst C, Engels EA, Strickler HD, Goedert JJ, Wagner J, and Mortimer EA Jr. (2001). Thirty-five year mortality following receipt of SV40- contaminated polio vaccine during the neonatal period. *British Journal of Cancer*, 85(9), 1295-1297.

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- 9 Strickler HD. (2001). A multicenter evaluation of assays for detection of SV40 DNA and results in masked mesothelioma. *Cancer Epidemiology Biomarkers and Prevalence*, 10(5), 523-532.
- 10 Institute of Medicine. (2002). *Immunization safety review: SV40 contamination of polio vaccine and cancer*. Washington, DC: National Academy Press. Available online: www.nap.edu/books/0309086108/html
- 11 Code of Federal Regulations (Title 9, Volume 1, Part 113). Available online: www.access.gpo.gov/nara/cfr/index.html#page1.

Recommended books and Web sites on this topic:

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

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

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

Offit PA and Bell LM. (1999). *Vaccines: What every parent should know* (Rev. ed.). New York: IDG Books.

National Partnership for Immunization. (2001). *Reference guide on vaccines and vaccine safety*. Washington, DC: Author. Available online: www.partnersforimmunization.org/pdf/toc.pdf