

# What makes up a vaccine?

Typically in Section 11 under "Description," the manufacturer will detail all ingredients that have been used in the creation and preservation of its product. According to the CDC, these ingredients fall within the following categories.



In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients.

Some excipients are added to a vaccine for a specific purpose. These include:

**Preservatives**, to prevent contamination. For example, thimerosal.

**Adjuvants**, to help stimulate a stronger immune response. For example, aluminum salts.

**Stabilizers**, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These can include:

**Cell culture materials**, used to grow the vaccine antigens. For example, egg protein, various culture media.

**Inactivating ingredients**, used to kill viruses or inactivate toxins. For example, formaldehyde.

**Antibiotics**, used to prevent contamination by bacteria. For example, neomycin.



It should be noted, although the CDC states here that residual trace amounts of materials used in the manufacturing process were removed, conflicting information is provided on another page of its website.

<sup>^</sup> Because influenza and yellow fever vaccines are both made in eggs, egg proteins are present in the final products. However, there are two new flu vaccines now available for people with egg allergies.

†Formaldehyde is diluted during the vaccine manufacturing process, but residual quantities of formaldehyde may be found in some current vaccines.



[cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf](https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf)  
[cdc.gov/vaccines/vac-gen/additives.htm](https://www.cdc.gov/vaccines/vac-gen/additives.htm)

## Manufacturing Residue

Let's dig deeper into some of the ingredients used in manufacturing. Unfortunately, the FDA and CDC do not have much information about the "manufacturing residue" listed in this CDC-linked excipients graph.

Excipient ▼	Purpose ▼	Vaccine Name ▼	Vaccine Type ▼	Amount per Dose
MRC-5	Manufacturing Residue	Havrix	HepA	≤5 mcg/mL
MRC-5	Manufacturing Residue	Zostavax	Varicella Zoster	Residual
MRC-5	Manufacturing Residue	Varivax	Varicella	Residual components
MRC-5	Manufacturing Residue	Imovax	Rabies	Amount not specified in Package Insert
MRC-5	Manufacturing Residue	ProQuad	MMRV	Residual
MRC-5	Manufacturing Residue	Twinrix	HepA+HepB	≤2.5 mcg
MRC-5	Manufacturing Residue	Vaqta	HepA	Amount not specified in Package Insert
MRC-5	Manufacturing Residue	Quadracel	DTaP+IPV	Ingredient in growth medium
Thimerosal	Manufacturing Residue	Td (generic)	Td	≤0.3 mcg mercury (trace amounts)

However, several manufacturers disclose MRC-5 and WI-38 are **human diploid cells**

### 11 DESCRIPTION

HAVRIX (Hepatitis A Vaccine) is a sterile suspension of inactivated virus for intramuscular administration. The virus (strain HM175) is propagated in MRC-5 human diploid cells.

### 11 DESCRIPTION

VARIVAX [Varicella Virus Vaccine Live] is a preparation of the Oka/Merck strain of live, attenuated varicella virus. The virus was initially obtained from a child with wild-type varicella, then introduced into human embryonic lung cell cultures, adapted to and propagated in embryonic guinea pig cell cultures and finally propagated in human diploid cell cultures (WI-38). Further passage of the virus for varicella vaccine was performed at Merck Research Laboratories (MRL) in human diploid cell cultures (MRC-5) that were free of adventitious agents. This live, attenuated varicella vaccine is a lyophilized preparation containing sucrose, phosphate, glutamate, processed gelatin, and urea as stabilizers.

[vaccinesafety.edu/components-Excipients.htm](https://vaccinesafety.edu/components-Excipients.htm)



### Vaccine for humans prepared in human diploid cells

An inactivated rabies vaccine for human use was first prepared in cell culture in 1964. In 1966 it was shown that the human diploid cell (HDC) strain WI-38 was a suitable substrate for the propagation of the Pitman-Moore (PM) strain of fixed rabies virus. The original procedure for the production of this vaccine was described in the third edition. Since 1967, research and development have been carried out on this vaccine at the Mérieux Institute. The vaccine was first licensed for use in France in 1974 and commercial production started in 1978.

The late 1970s and the 1980s saw the development of a plethora of vaccines prepared on various cellular substrates such as primary explant cells of hamster, dog or fetal calf kidney, fibroblasts of chicken embryo, or diploid cells from rhesus monkey fetal lung, and finally cells from continuous lines (Vero cells). The production of some of these vaccines was stopped at the end of the 1980s whilst others have been administered to millions of patients.

[who.int/rabies/vaccines/human\\_vaccines/en/](http://who.int/rabies/vaccines/human_vaccines/en/)

## DOES THE HUMAN DNA TRANSFER TO THE PATIENT?

Again, unfortunately the CDC/FDA do not provide much information, however this CDC-referenced excipients list populated from manufacturer inserts states DNA is transferred to the patient.

### Excipients in Vaccines per 0.5 mL dose

Excipient ▼	Purpose ▼	Vaccine Name ▼	Vaccine Type ▼	Amount per Dose
DNA	Residual Medium	Shingrix	Zoster	≤2.1 pg
DNA	Residual Medium	Zostavax	Zoster	Residual component of MRC-5 cells
DNA	Residual Medium	Varivax	Varicella	Residual component of MRC-5 cells
DNA	Residual Medium	RotaTeq	Rotavirus	Residual component of manufacturing process
DNA	Residual Medium	ProQuad	MMRV	Residual component of MRC-5 cells
DNA	Residual Medium	Ixiaro	Japanese Encephalitis	≤200 pg/mL ('host cell DNA')
DNA	Residual Medium	Flublok	Influenza	≤10 ng
DNA	Residual Medium	Flublok Quad	Influenza	≤10 ng
DNA	Residual Medium	Flucelvax Quad	Influenza	≤10 ng MDCK cell
DNA	Residual Medium	Vaqa	HepA	<4 x 10 <sup>-6</sup> mcg

It is unclear the implications of these residual amounts especially when Section 13.1 in manufacturer inserts states vaccines have not been evaluated for mutagenic potential.

**Mutagen**, any agent capable of altering the genetic constitution of a cell by changing the structure of the hereditary material, deoxyribonucleic acid (DNA).

## WHAT IF I CAN'T HAVE SOME OF THESE INGREDIENTS?

As stated already, those with egg allergies should absolutely avoid any product with residual egg. Additionally, there are several scenerios where individuals may oppose certain ingredients.

*Vegans* may oppose the use of gelatin (derived from pigs), eggs, lactose (derived from milk whey), human, and animal cells such as african green monkeys, mouse serum protein, fetal bovine serum, canine kidney cells, and squalene based oil-in-water (shark liver oil) for example.

*Kosher and Halal*

are examples of religious dietary restrictions that would also be compromised by these products.

*Pro-life advocates* may oppose

human cells because they were derived from multiple abortions.

## WHAT ABOUT THIMEROSAL?

**Thimerosal is a mercury-containing organic compound**

## FDA Actions Pertaining to Thimerosal in Vaccines

FDA has actively addressed the issue of thimerosal as a preservative in vaccines. The use of thimerosal as a preservative in U.S. FDA-licensed vaccines has significantly declined due to reformulation and development of new vaccines presented in single-dose containers. Under the FDA Modernization Act (FDAMA) of 1997, the FDA conducted a comprehensive review of the use of thimerosal in childhood vaccines.

As part of the FDAMA review, the FDA evaluated the amount of mercury an infant might receive in the form of ethylmercury from vaccines under the U.S. recommended childhood immunization schedule and compared these levels with existing guidelines for exposure to methylmercury, as there are no existing guidelines for ethylmercury, the metabolite of thimerosal.

However, depending on the vaccine formulations used and the weight of the infant, some infants could have been exposed to cumulative levels of mercury during the first six months of life that exceeded Environmental Protection Agency (EPA) recommended guidelines for safe intake of methylmercury.

Other than allergic responses in some individuals, there was no known health risk from thimerosal-preservative at the concentration used in vaccines, but in 1999, the Public Health Service (including the FDA, National Institutes of Health (NIH), CDC, and Health Resources and Services Administration (HRSA)), along with the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) concluded that because of scientific uncertainty at the time, as a precautionary measure, that it was prudent to reduce childhood exposure to mercury from all sources, including vaccines, as feasible.

Much progress has been made in removing or reducing thimerosal in vaccines. All vaccines routinely recommended for children 6 years of age and younger in the U.S. are available in formulations that do not contain thimerosal. In addition, vaccines that do not contain thimerosal as a preservative are available for adolescents and adults.

[fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines#action](https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines#action)

## THIMEROSAL FOR 6 MONTH OLDS?

According to the CDC, the following vaccines still contain thimerosal:

Td (tetanus), Menomune (meningococcal), JE-Vax (Japanese Encephalitis) as well as these flu vaccines: Afluria, **Afluria Quad**, Flucelvax Quad, **Flulaval Quad**, Fluvirin, and **Fluzone Quad**

\*Bolded flu products are currently recommended by the CDC for **children 6 months+**

Why does the CDC **currently** recommend products with thimerosal to children starting at 6 months of age when the FDA states it is "prudent to reduce childhood exposure to mercury from all sources, including vaccines...?"

### U.S. Influenza Vaccine Products for the 2020-21 Season

Trade Name [Manufacturer]	Presentation	Age Indication	HA, µg/dose (each virus)	Thimerosal Yes/No If yes, Mercury, µg/0.5mL
Afluria Quadrivalent* Seqirus	5.0 mL multi-dose vial*	≥6 mos(needle/syringe) 18 through 64 yrs (jet injector)		Yes (24.5)
Fluzone Quadrivalent† Sanofi Pasteur	5.0 mL multi-dose vial†	≥6 mos		Yes (25)

[cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm](https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm)