

## Vaccine Excipient & Media Summary Excipients Included in U.S. Vaccines, by Vaccine

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

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 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.

The following table lists all components, other than antigens, shown in the manufacturers' package insert (PI) for each vaccine. Each of these PIs, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

**All information was extracted from manufacturers' package inserts, current as of January 6, 2017.** If in doubt about whether a PI has been updated

since then, check the FDA's website at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

### Vaccine Contains

#### Adenovirus

human-diploid fibroblast cell cultures (strain WI-38), Dulbecco's Modified Eagle's Medium, fetal bovine serum, sodium bicarbonate, monosodium glutamate, sucrose, D-mannose, D- fructose, dextrose, human serum albumin, potassium phosphate, pladone C, anhydrous lactose, microcrystalline cellulose, polacrillin potassium, magnesium stearate, microcrystalline cellulose, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye

#### Anthrax (Biothrax)

amino acids, vitamins, inorganic salts, sugars, aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde

#### BCG (Tice)

glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose

#### Cholera (Vaxchora)

casamino acids, yeast extract, mineral salts, anti-foaming agent, ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate

#### DT (Sanofi)

aluminum phosphate, isotonic sodium chloride, formaldehyde, casein, cystine, maltose, uracil, inorganic salts, vitamins, dextrose

#### DTaP (Daptacel)

aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid

medium without beef heart infusion, 2-phenoxyethanol

DTaP (Infanrix)

Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)

DTaP-IPV (Kinrix)

Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, VERO cells, a continuous line of monkey kidney cells, Calf serum, lactalbumin hydrolysate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B

DTaP-IPV (Quadracel)

modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, formaldehyde, ammonium sulfate aluminum phosphate, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, MRC-5 cells, normal human diploid cells, CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate

## Vaccine Contains

### DTaP-HepB-IPV (Pediarix)

Fenton medium containing a bovine extract, modified Latham medium derived from bovine casein, formaldehyde, modified Stainer-Scholte liquid medium, VERO cells, a continuous line of monkey kidney cells, calf serum and lactalbumin hydrolysate, aluminum hydroxide, aluminum phosphate, aluminum salts, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein.

### DTaP-IPV/Hib (Pentacel)

aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. glutaraldehyde, MRC-5 cells (a line of normal human diploid cells), CMRL 1969 medium supplemented with calf serum, Medium 199 without calf serum, modified Mueller and Miller medium

### Hib (ActHIB)

sodium chloride, modified Mueller and Miller medium (the culture medium contains milk- derived raw materials [casein derivatives]), formaldehyde, sucrose Hib (Hiberix) saline, synthetic medium, formaldehyde, sodium chloride, lactose

### Hib (PevaxHIB)

complex fermentation media, amorphous aluminum hydroxyphosphate sulfate, sodium chloride Hib/Mening. CY (MenHibrix) saline, semi-synthetic media, formaldehyde, sucrose, tris (trometamol)-HCl

### Hep A (Havrix)

MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic

### Hep A (Vaqta)

MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride

### Hep B (Engerix-B)

aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate

### Hep B (Recombivax)

soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein

### Hep A/Hep B (Twinrix)

MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein Human Papillomavirus (HPV) (Gardasil)

vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein Human Papillomavirus (HPV) (Gardasil 9)

vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein

### Influenza (Afluria) Trivalent & Quadrivalent

sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)

Influenza (Fluad)

squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, egg proteins, CTAB (cetyltrimethylammonium bromide), formaldehyde

Influenza (Fluarix) Trivalent & Quadrivalent

octoxynol-10 (TRITON X-100),  $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride

Influenza (Flublok) Trivalent & Quadrivalent

sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts Influenza (Flucelvax) Trivalent & Quadrivalent

Madin Darby Canine Kidney (MDCK) cell protein, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and  $\beta$ -propiolactone Influenza (Flulaval) Trivalent & Quadrivalent

ovalbumin, formaldehyde, sodium deoxycholate,  $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials) Influenza (Fluvirin) ovalbumin, polymyxin, neomycin, betapropiolactone, nonylphenol ethoxylate, thimerosal Influenza (Fluzone) Quadrivalent

formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials), sucrose

#### Vaccine Contains Influenza (Fluzone) High Dose

egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, sucrose Influenza (Fluzone) Intradermal

egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, sucrose

#### Influenza (FluMist) Quadrivalent

monosodium glutamate, hydrolyzed porcine **gelatin**, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA) Japanese Encephalitis (Ixiaro)

aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein Meningococcal (MenACWY-Menactra)

Watson Scherp media containing casamino acid, modified culture medium containing hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride Meningococcal (MenACWY-Menveo)

formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium

#### Meningococcal (MPSV4-Menomune)

Mueller Hinton casein agar, Watson Scherp casamino acid media, thimerosal (multi-dose vials), lactose Meningococcal (MenB – Bexsero)

aluminum hydroxide, E. coli, histidine, sucrose, deoxycholate, kanamycin

#### Meningococcal (MenB – Trumenba)

defined fermentation growth media, polysorbate 80, histidine buffered saline.

#### MMR (MMR-II)

chick embryo cell culture, WI-38 human diploid lung fibroblasts, vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed **gelatin**, sodium phosphate, sodium chloride

#### MMRV (ProQuad) (Frozen)

chick embryo cell culture, WI-38 human diploid lung fibroblasts MRC-5 cells, sucrose, hydrolyzed **gelatin**, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, **bovine** calf serum

#### MMRV (ProQuad) (Refrigerator Stable)

chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed **gelatin**, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate potassium chloride, neomycin, **bovine** serum albumin Pneumococcal (PCV13 – Pevnar 13)

soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, polysorbate 80, succinate buffer, aluminum phosphate Pneumococcal (PPSV-23 – Pneumovax)

phenol

#### Polio (IPV – Ipol)

Eagle MEM modified medium, calf **bovine** serum, M-199 without calf **bovine** serum, vero cells (a continuous line of monkey kidney cells), phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B

Rabies (Imovax)

human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta- propiolactone

Rabies (RabAvert)

chicken fibroblasts,  $\beta$ -propiolactone, polygeline (processed **bovine gelatin**), human serum albumin, **bovine** serum, potassium glutamate, sodium EDTA, ovalbumin neomycin, chlortetracycline, amphotericin B

Rotavirus (RotaTeq)

sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal **bovine** serum, vero cells [DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]

Rotavirus (Rotarix)

amino acids, dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D- glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-250 glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan [Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.] Smallpox (Vaccinia – ACAM2000)

African Green Monkey kidney (Vero) cells, HEPES, human serum albumin, sodium chloride, neomycin, polymyxin B, Glycerin, phenol

## Vaccine Contains

Td (Tenivac)

aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without **beef** heart infusion, ammonium sulfate

Td (Mass Biologics)

aluminum phosphate, formaldehyde, thimerosal, modified Mueller's media which contains **bovine** extracts, ammonium sulfate

Tdap (Adacel)

aluminum phosphate, formaldehyde, 2-phenoxyethanol, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin, glutaraldehyde, modified Mueller-Miller casamino acid medium without **beef** heart infusion, ammonium sulfate, modified Mueller's growth medium

Tdap (Boostrix)

modified Latham medium derived from **bovine** casein, Fenton medium containing a **bovine** extract, formaldehyde, modified Stainer-Scholte liquid medium, glutaraldehyde, aluminum hydroxide, sodium chloride, polysorbate 80  
Typhoid (inactivated – Typhim Vi)

hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium

Typhoid (Vivotif Ty21a)

yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. **gelatin**

Varicella (Varivax) Frozen

human embryonic lung cell cultures, guinea **pig** cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed **gelatin**, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, EDTA (Ethylenediaminetetraacetic acid), neomycin, fetal **bovine** serum

Varicella (Varivax) Refrigerator Stable

human embryonic lung cell cultures, guinea **pig** cell cultures, human diploid cell cultures (WI-38), human diploid cell cultures (MRC-5), sucrose, hydrolyzed **gelatin**, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, **bovine** calf serum Yellow Fever (YF-Vax) sorbitol, **gelatin**, sodium chloride, egg protein Zoster (Shingles – Zostavax) Frozen

sucrose, hydrolyzed porcine **gelatin**, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; MRC-5 cells, neomycin, **bovine** calf serum Zoster (Shingles – Zostavax)  
Refrigerator Stable

sucrose, hydrolyzed porcine **gelatin**, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 cells, neomycin, **bovine** calf serum

A table listing vaccine excipients and media by excipient can be found in:

Grabenstein JD. ImmunoFacts: Vaccines and Immunologic Drugs – 2013 (38th revision). St Louis, MO: Wolters Kluwer Health, 2012.















