

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 (Pediatrix) | 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 (PedvaxHIB) | 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), α -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 <i>Spodoptera frugiperda</i> 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 β -propiolactone |
| Influenza (Flulaval) Trivalent & Quadrivalent | ovalbumin, formaldehyde, sodium deoxycholate, α -tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials) |
| Influenza (Fluvirin) | ovalbumin, polymyxin, neomycin, betapropiolactone, nonylphenol ethoxylate, thimerosal |
| Influenza (Fluzone) Quadrivalent | 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, <i>E. coli</i> , 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 – Prevnar 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, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin neomycin, chlortetracycline, amphotericin B |
| Rotavirus (RotaTaq) | sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells [<i>DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTaq. PCV-1 and PCV-2 are not known to cause disease in humans.</i>] |
| 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 [<i>Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.</i>] |
| 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) <i>Frozen</i> | 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) <i>Refrigerator Stable</i> | 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) <i>Frozen</i> | 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) <i>Refrigerator Stable</i> | 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.