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.

If in doubt about whether a PI has been updated since this table was prepared, 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, plasdone C, anhydrous |
| | lactose, microcrystalline cellulose, polacrilin potassium, 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 |
| | aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, Stainer-Scholte |
| DTaP (Daptacel) | medium, casamino acids, dimethyl-beta-cyclodextrin, Mueller's growth medium, |
| | ammonium sulfate, modified Mueller-Miller casamino acid medium without beef heart |
| | infusion |
| | Fenton medium containing a bovine extract, modified Latham medium derived from bovine |
| DTaP (Infanrix) | 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, 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, glutaraldehyde, 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. |
| | aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum |
| | albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate, modified Mueller's growth |
| DTaP-IPV/Hib (Pentacel) | medium, ammonium sulfate, modified Mueller-Miller casamino acid medium without beef |
| | heart infusion, Stainer-Scholte medium, casamino acids, dimethyl-beta-cyclodextrin. 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- |
| Hil (Hilbania) | 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 |
| | MRC-5 human diploid cells, formalin, aluminum hydroxide, amino acid supplement, |
| Hep A (Havrix) | phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside |
| T \ | antibiotic |
| Hep A (Vaqta) | MRC-5 diploid fibroblasts, amorphous aluminum hydroxyphosphate sulfate, non-viral |
| Hep A (Vaqta) | protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride |
| Hep B (Engerix-B) | aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium |
| · r · · · · · · · · · · · · · · · · · · | dihydrogen phosphate dihydrate |
| Hen B (Recombiyay) | soy peptone, dextrose, amino acids, mineral salts, phosphate buffer, formaldehyde, |
| Hep B (Recombivax) | potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein |
| | vitamins and mineral salts, yeast protein, yeast DNA, deoxycholate, phosphorothioate linked |
| Hep B (Heplisav-B) | oligodeoxynucleotide, phosphate buffered saline, sodium phosphate, dibasic dodecahydrate, |
| | monobasic dehydrate, polysorbate 80 |
| Hep A/Hep B (Twinrix) | MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino |
| Human Papillomavirus | acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate |
| (HPV) (Gardasil 9) | sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein |
| (III v) (Gurdusii y) | sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic |
| Influenza (Afluria) | potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, |
| Trivalent & Quadrivalent | ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi- |
| | dose vials) |
| | squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid |
| Influenza (Fluad) | monohydrate, neomycin, kanamycin, barium, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde |
| | octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween |
| Influenza (Fluarix) | 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, |
| Quadrivalent | sodium phosphate-buffered isotonic sodium chloride |
| Influenza (Flublok) | sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 |
| Quadrivalent | (Tween 20), baculovirus and <i>Spodoptera frugiperda</i> cell proteins, baculovirus and cellular |
| Quadrivalent | DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts |
| Influenza (Flucelvax) Quadrivalent | Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other |
| | than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone, Thimerosal (multi-dose vials) |
| Influenza (Flulaval) | ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, |
| Quadrivalent | polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution |
| Influenza (Fluzone) | formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate- |
| Quadrivalent | buffered isotonic sodium chloride solution, thimerosal (multi-dose vials) |
| | , |

| Vaccine | Contains |
|---|--|
| Influenza (Fluzone) | egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic |
| High Dose | sodium chloride solution, formaldehyde monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium |
| Influenza (FluMist) Quadrivalent | phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, |
| | ethylenediaminetetraacetic acid (EDTA) |
| Japanese Encephalitis | aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell |
| (Ixiaro) | DNA, sodium metabisulphite, host cell protein |
| Meningococcal | Watson Scherp media containing casamino acid, modified culture medium containing |
| (MenACWY-Menactra) | hydrolyzed casein, ammonium sulfate, sodium phosphate, formaldehyde, sodium chloride |
| Meningococcal (MenACWY-Menveo) | formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium |
| Meningococcal (MenB – Bexsero) | aluminum hydroxide, E. coli, histidine, sucrose, deoxycholate, kanamycin |
| Meningococcal (MenB – Trumenba) | defined fermentation growth media, polysorbate 80, aluminum phosphate, 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 |
| | chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, |
| MMRV (ProQuad) | hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate |
| (Frozen) | dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium |
| | chloride; potassium phosphate dibasic, neomycin, bovine calf serum |
| MMDV (Dro Oved) | chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium |
| MMRV (ProQuad) (Refrigerator Stable) | phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, |
| (Reingerator Stable) | potassium chloride, neomycin, bovine serum albumin |
| Pneumococcal | soy peptone broth, casamino acids and yeast extract-based medium, CRM197 carrier protein, |
| (PCV13 – Prevnar 13) | 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- propriolactone |
| Rabies (RabAvert) | chicken fibroblasts, β-propiolactone, polygeline (processed bovine gelatin), human serum albumin, bovine serum, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B |
| | sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, |
| Rotavirus (RotaTeq) | polysorbate 80, cell culture media, fetal bovine serum, vero cells [DNA from porcine |
| Rotavirus (Rota req) | circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known |
| | to cause disease in humans.] |
| | Vero cells, 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- |
| Rotavirus (Rotarix) | 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, 2% human serum albumin, 0.7% |
| | sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, |
| (| 0.25% phenol USP |
| Td (Tenivac) | aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate, sodium chloride, water |

| Vaccine | Contains |
|--|---|
| 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 (Typhim Vi) | hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium, sodium chloride, sterile water |
| Typhoid (Vivotif Ty21a) | yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin |
| Varicella (Varivax) Frozen | MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum |
| Varicella (Varivax) Refrigerator Stable | MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, 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 | MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; neomycin, bovine calf serum |
| Zoster (Shingles) (Zostavax) | MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium |
| Refrigerator Stable | phosphate monobasic, potassium chloride, neomycin, bovine calf serum |
| Zoster (Shingles) (Shingrix) | sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3- <i>O</i> -desacl- 4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract <i>Quillaja</i> saponaria Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80 |

A table listing vaccine excipients and media *by excipient* is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at http://www.vaccinesafety.edu/components-Excipients.htm.

Updates:

Trumenba: (added Aluminum phosphate)

RotaTeq: PI dated 2/2017

Rotarix: 6/11/18 (PI dated xx/xxxx)

Smallpox: 3/2018 Td (Tenivac): April 2013

Td (Mass Biologics): April 2009 (no change) Tdap (Adacel): xxx/2017 (no change)

Tdap (Boostrix): 6/12/2018 (PI dated xx/xxxx) (no change)

Typhim Vi: March 2014 (added sodium chloride & buffered saline) Ty21a: September 2013

Varicella Frozen: 2/2017

Varicella Refrigerator Stable: 2/2017

YF Vax: June 2016 Zostivax Frozen: xx/2018

Zostivax Refrigerator Stable: xx/2018

Shingrix: 10/2017