

## Vaccine Excipient Summary

### Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (such as weakened, killed, or parts of 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.

The following table lists substances, other than active ingredients (i.e., antigens), shown in the manufacturers' package insert (PI) as being contained in the final formulation of each vaccine. **Substances used in the manufacture of a vaccine but not listed as contained in the final product (e.g., culture media) can be found in each PI, but are not shown on this table.** Each PI, 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." Please refer to the PI for a complete list of ingredients or excipients. 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>.

# Appendix B

## Vaccine Excipient Table

Vaccine (Trade Name)	Package Insert Date	Contains <sup>(a)</sup>
Adenovirus	10/2019	monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdane C, anhydrous lactose, microcrystalline cellulose, polacrillin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	11/2015	aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	02/2009	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	06/2016	ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
Dengue (Dengvaxia)	06/2019	sodium chloride, essential amino acids (including L-phenylalanine), non-essential amino acids, L-arginine hydrochloride, sucrose, D-trehalose dihydrate, D-sorbitol, trometamol, urea
DT (Sanofi)	06/2018	aluminum phosphate, isotonic sodium chloride, formaldehyde
DTaP (Daptacel)	01/2021 <sup>(b)</sup>	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol
DTaP (Infanrix)	01/2021 <sup>(b)</sup>	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	01/2021 <sup>(b)</sup>	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	02/2021	formaldehyde, aluminum phosphate, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate, bovine serum albumin
DTaP-HepB-IPV (Pediatrix)	01/2021 <sup>(b)</sup>	formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein
DTaP-IPV/Hib (Pentacel)	12/2019	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate
DTaP-IPV-Hib-HepB (Vaxelis)	10/2020	polysorbate 80, formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, streptomycin sulfate, polymyxin B sulfate, ammonium thiocyanate, yeast protein, aluminum
Ebola Zaire (ERVEBO)	01/2021 <sup>(b)</sup>	Tromethamine, rice-derived recombinant human serum albumin, host cell DNA, benzonase, rice protein
Hib (ActHIB)	05/2019	sodium chloride, formaldehyde, sucrose
Hib (Hiberix)	04/2018	formaldehyde, sodium chloride, lactose
Hib (PevaxHIB)	01/2021 <sup>(b)</sup>	amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hep A (Havrix)	01/2021 <sup>(b)</sup>	MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	01/2021 <sup>(b)</sup>	amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals
Hep B (Engerix-B)	01/2021 <sup>(b)</sup>	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	12/2018	formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
Hep B (Heplisav-B)	05/2020	yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, sodium phosphate, dibasic dodecahydrate, sodium chloride, monobasic dehydrate, polysorbate 80
Hep A/Hep B (Twinrix)	01/2021 <sup>(b)</sup>	MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein
HPV (Gardasil 9)	08/2020	amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein

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Vaccine (Trade Name)	Package Insert Date	Contains <sup>(a)</sup>
Influenza (Afluria) Quadrivalent <sup>(c)</sup>	03/2021	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, hydrocortisone, thimerosal (multi-dose vials)
Influenza (Fluad) Quadrivalent <sup>(c)</sup>	03/2021	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, hydrocortisone, egg protein, formaldehyde
Influenza (Fluarix) Quadrivalent <sup>(c)</sup>	2021	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) Quadrivalent <sup>(c)</sup>	03/2021	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
Influenza (Flucelvax) Quadrivalent <sup>(c)</sup>	10/2021 <sup>(b)</sup>	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and $\beta$ -propiolactone, thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent <sup>(c)</sup>	2021	ovalbumin, formaldehyde, sodium deoxycholate, $\alpha$ -tocopheryl hydrogen succinate, polysorbate 80, phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent <sup>(c)</sup>	2021	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)
Influenza (Fluzone) High Dose <sup>(c)</sup>	07/2021	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
Influenza (FluMist) Quadrivalent <sup>(c)</sup>	08/2021	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
IPV (Ipol)	01/2021 <sup>(b)</sup>	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium
Japanese Encephalitis (Ixiaro)	09/2018	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite, host cell protein
MenACWY (Menactra)	04/2018	sodium phosphate buffered isotonic sodium chloride solution, formaldehyde, diphtheria toxoid protein carrier
MenACWY (MenQuadfi)	01/2021 <sup>(b)</sup>	sodium chloride, sodium acetate, formaldehyde
MenACWY (Menveo)	07/2020	formaldehyde, CRM <sub>197</sub> protein
MenB (Bexsero)	01/2021 <sup>(b)</sup>	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB (Trumenba)	2018	polysorbate 80, aluminum phosphate, histidine buffered saline
MMR (MMR-II)	12/2020	sorbitol, sucrose, hydrolyzed gelatin, recombinant human albumin, neomycin, fetal bovine serum, WI-38 human diploid lung fibroblasts
MMRV (ProQuad) (Frozen: Recombinant Albumin)	01/2021 <sup>(b)</sup>	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, other buffer and media ingredients
PCV13 (Pevnar 13)	08/2017	CRM <sub>197</sub> carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
PPSV-23 (Pneumovax)	09/2020	isotonic saline solution, phenol
Rabies (Imovax)	10/2019	human albumin, neomycin sulfate, phenol red, beta-propiolactone
Rabies (RabAvert)	2018	chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTaq)	01/2021 <sup>(b)</sup>	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum

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Vaccine (Trade Name)	Package Insert Date	Contains <sup>(a)</sup>
Rotavirus (Rotarix)	01/2021 <sup>(b)</sup>	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, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan [Porcine circovirus type 1 (PCV1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]
Smallpox (Vaccinia) (ACAM2000)	03/2018	HEPES, 2% human serum albumin, 0.5 - 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP
Td (Tenivac)	11/2019	aluminum phosphate, formaldehyde, sodium chloride
Td (TDVAX)	09/2018	aluminum phosphate, formaldehyde, thimerosal
Tdap (Adacel)	12/2020	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde
Tdap (Boostrix)	09/2020	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (Typhim Vi)	03/2020	formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, sodium chloride
Typhoid (Vivotif Ty21a)	9/2013	sucrose, ascorbic acid, amino acids, lactose, magnesium stearate, gelatin
Varicella (Varivax) Frozen	01/2021 <sup>(b)</sup>	sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 human diploid cells including DNA & protein, sodium phosphate monobasic, EDTA, neomycin, fetal bovine serum
Yellow Fever (YF-Vax)	2/2019	sorbitol, gelatin, sodium chloride
Zoster (Shingles) (Shingrix)	01/2021 <sup>(b)</sup>	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-O-desacetyl-4'-monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract <i>Quillaja saponaria</i> Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA

**Abbreviations:** DT = diphtheria and tetanus toxoids; DTaP = diphtheria and tetanus toxoids and acellular pertussis; Hep A = Hepatitis A; Hep B = Hepatitis B; Hib = *Haemophilus influenzae* type b; HPV = human papillomavirus; IPV = inactivated poliovirus; LAIV = live, attenuated influenza vaccine; MenACWY = quadrivalent meningococcal conjugate vaccine; MenB = serogroup B meningococcal vaccine; MMR = measles, mumps, and rubella; MMRV = measles, mumps, rubella, varicella; PCV13 = pneumococcal conjugate vaccine; PPSV23 = pneumococcal polysaccharide vaccine; Td = tetanus and diphtheria toxoids; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis.

<sup>(a)</sup>All information was extracted from manufacturers' package inserts. The date shown in the Date column of the table is the edition date of the PI in use in January 2021 by month and year. In some cases, only a year was printed on the PI. 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>

<sup>(b)</sup>The PI was not dated and this is the date the PI was reviewed for this table.

<sup>(c)</sup>All influenza vaccine in this table are 2021-22 northern hemisphere formulation.

November 2021

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