

Appendix 1 – Contents of Section 13.1 in Vaccines’ Package Inserts

Table 1A-1 - Contents of Section 13.1 in Vaccines’ Package Inserts

(Note: Asterisk (*) in leftmost column denotes disease that vaccine is designed to prevent)

D	VACCINE	CONTENTS OF SECTION 13.1 IN VACCINE INSERT
*	Adenovirus	
	(Adenovirus Type 4 and Type 7)	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility.
*	Anthrax	
	AVA (BioThrax)	The effect of BioThrax on embryo-fetal and pre-weaning development was evaluated in a developmental toxicity study using pregnant rabbits. One group of rabbits was administered BioThrax twice prior to gestation and during the period of organogenesis (gestation day 7). A second group of rabbits was administered BioThrax twice prior to gestation and on gestation day 17. BioThrax was administered at 0.5 ml/rabbit/occasion, by intramuscular injection. No adverse effects on mating, fertility, pregnancy, parturition, lactation, embryo-fetal or preweaning development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis noted in this study.
	(CYFENDUS)	CYFENDUS has not been evaluated for carcinogenicity, mutagenic potential, or male infertility in animals. CYFENDUS administered to female rats had no effect on fertility
*	Chikungunya Virus	
	(IXCHIQ)	IXCHIQ has not been evaluated for carcinogenic or mutagenic potential or impairment of male fertility. In a developmental toxicity study conducted in rats, there were no vaccine-related effects on female fertility
*	Cholera	
	(Vaxchora)	VAXCHORA has not been evaluated for the potential to cause carcinogenicity or genotoxicity, or to impair fertility.
*	Covid-19	
	(COMIRNATY)	COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. In a developmental toxicity study in rats with COMIRNATY [encoding the viral spike (S) glycoprotein of SARS-CoV-2 Wuhan-Hu 1 strain (Original)] there were no vaccine-related effects on female fertility
	(MODERNA-EUA)	Section 13 was not included
	(NOVAVAX-EUA)	Section 13 was not included
	(PFIZER-BIONTECH-EUA)	Section 13 was not included
	(SPIKEVAX)	SPIKEVAX has not been evaluated for carcinogenic, mutagenic potential, or impairment of male fertility in animals. A developmental toxicity study was conducted in female rats that received a vaccine formulation containing nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other

		ingredients included in a single human dose of SPIKEVAX. No impact on female fertility was reported
*	Dengue	
	(DENGIVAXIA)	DENGIVAXIA has not been evaluated for carcinogenic or mutagenic potential or impairment of male fertility. Exposure of female rabbits to DENGIVAXIA prior to and during gestation did not impair fertility.
*	Diphtheria	
	DTaP (Daptacel)	DAPTACEL has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP (Infanrix)	INFANRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 14 fertility.
	Td (Tenivac)	TENIVAC has not been evaluated for carcinogenic or mutagenic potential or impairment of male fertility in animals. Vaccination of female rabbits with TENIVAC had no effects on fertility.
	Td (generic)	No studies have been performed with MassBiologics' TDVAX to evaluate carcinogenicity, mutagenic potential, or impairment of fertility.....PREGNANCY Animal reproduction studies have not been conducted with MassBiologics' TDVAX. It is also not known whether MassBiologics' TDVAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. MassBiologics' TDVAX should be given to a pregnant woman only if clearly needed....NURSING MOTHERS It is not known whether MassBiologics' TDVAX is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when MassBiologics' TDVAX is administered to a nursing woman.
	Tdap (Adacel)	Adacel has not been evaluated for carcinogenic or mutagenic potential, or impairment of male fertility.
	Tdap (Boostrix)	BOOSTRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits and rats with BOOSTRIX had no effect on fertility.
	DTaP-IPV (Kinrix)	KINRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	DTaP-IPV (Quadracel)	Quadracel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-HepB-IPV (Pediarix)	PEDIARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 16 fertility.
	DTaP-IPV/Hib (Pentacel)	Pentacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-IPV-Hib-HepB (Vaxelis)	VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
*	Ebola	
	(ERVEBO)	ERVEBO has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility. ERVEBO administered to female rats had no effects on fertility
*	Encephalitis	
	Tick-borne encephalitis (Ticovac)	TICOVAC has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of fertility.

*	Hepatitis A	
	HepA (Havrix)	HAVRIX has not been evaluated for its carcinogenic potential, mutagenic potential, or potential for impairment of fertility.
	HepA (Vaqta)	VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.
	HepA-HepB (Twinrix)	TWINRIX has not been evaluated for its carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rats with TWINRIX had no effect on fertility.
*	Hepatitis B	
	HepB (Engerix-B)	ENGERIX-B has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rats with TWINRIX, which contains the same HBsAg component and quantity as ENGERIX-B, had no effect on fertility.
	HepB (Recombivax HB)	RECOMBIVAX HB has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility
	HepB (Heplisav-B)	HEPLISAV-B has not been evaluated for carcinogenicity, mutagenic potential or male infertility in animals. Vaccination of female rats with a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg CpG 1018 adjuvant had no effect on fertility
	HepB (PreHevbrio)	PREHEVBRIO has not been evaluated for carcinogenic, mutagenic potential or male infertility in animals. In a developmental toxicity study in rats with a vaccine formulation containing 10 mcg HBsAg (S, pre-S1, pre-S2) adsorbed on to aluminum hydroxide there were no effects on female fertility
	DTaP-HepB-IPV (Pediarix)	PEDIARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 16 fertility.
	HepA-HepB (Twinrix)	TWINRIX has not been evaluated for its carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rats with TWINRIX had no effect on fertility.
	DTaP-IPV-Hib-HepB (Vaxelis)	VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
*	Haemophilus influenzae type b (Hib)	
	Hib (ActHIB)	ActHIB vaccine has not been evaluated for its carcinogenic or mutagenic potential or impairment of male fertility.
	Hib (PedvaxHIB)	Section 13 was not included
	Hib (Hiberix)	HIBERIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.
	DTaP-IPV/Hib (Pentacel)	Pentacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-IPV-Hib-HepB (Vaxelis)	VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
*	Human Papillomavirus (HPV)	
	HPV9 (Gardasil 9)	GARDASIL 9 has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility.

*	Influenza	
	IIV (Afluria)	AFLURIA QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential, or male infertility in animals. A developmental toxicity study conducted in rats vaccinated with AFLURIA (trivalent formulation) revealed no impact on female fertility
	IIV (Fluad)	FLUAD QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. FLUAD (trivalent formulation) did not affect female fertility in a rabbit developmental toxicity study
	IIV (Flublok)	Flublok Quadrivalent has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. A developmental toxicity study conducted in rats vaccinated with Flublok (trivalent formulation) revealed no evidence of impaired female fertility
	IIV (Flucelvax)	FLUCELVAX QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. FLUCELVAX (trivalent formulation) administered to female rabbits had no effect on fertility.
	IIV (FluLaval)	FLULAVAL QUADRIVALENT has not been evaluated for carcinogenic, mutagenic potential, or male infertility in animals. Vaccination of female rats with FLULAVAL QUADRIVALENT had no effect on fertility
	IIV (Fluarix)	FLUARIX QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential or male infertility in animals. Vaccination of female rats with FLUARIX QUADRIVALENT had no effect on fertility
	IIV (Fluvirin)	FLUVIRIN® has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.
	IIV (Fluzone)	Fluzone Quadrivalent has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits with Fluzone Quadrivalent revealed no evidence of impaired female fertility
	IIV (Fluzone High-Dose)	Fluzone High-Dose Quadrivalent has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	IIV (Fluzone Intradermal)	Fluzone Quadrivalent has not been evaluated for carcinogenic or mutagenic potential. A 8 reproductive study of female rabbits vaccinated with Fluzone Quadrivalent was performed and 9 revealed no evidence of impaired female fertility
	LAIV (FluMist)	FluMist Quadrivalent has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility.
*	Japanese Encephalitis	
	JE (Ixiaro)	IXIARO has not been evaluated for carcinogenic or mutagenic potential. IXIARO was found to have no effect on fertility of female rats.....The effect of IXIARO on male fertility has not been evaluated.
*	Measles	
	MMR (M-M-R II)	M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility
	MMR (Priorix)	PRIORIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.

	MMRV (ProQuad)	ProQuad has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility.
*	Meningococcal	
	MenACWY (Menactra)	Menactra has not been evaluated for carcinogenic or mutagenic potential, or for impairment of 17 male fertility. A developmental animal toxicity study showed that Menactra had no effects on 18 female fertility in mice
	MenACWY (MenQuadfi)	MenQuadfi has not been evaluated for carcinogenic or mutagenic potential or for impairment of male fertility. MenQuadfi administered to female rabbits had no effects on fertility
	MenACWY (Menveo)	MENVEO has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits with MENVEO had no effect on fertility.
	MenB (Bexsero)	BEXSERO has not been evaluated for carcinogenic or mutagenic potential or impairment of male fertility in animals. Vaccination of female rabbits with BEXSERO had no effect on fertility.
	MenB (Trumenba)	Trumenba has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility in males. Vaccination of female rabbits with Trumenba had no effect on fertility
*	Mumps	
	MMR (M-M-R II)	M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility
	MMR (Priorix)	PRIORIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	MMRV (ProQuad)	ProQuad has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility.
*	Pertussis	
	DTaP (Daptacel)	DAPTACEL has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP (Infanrix)	INFANRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 14 fertility.
	Tdap (Adacel)	Adacel has not been evaluated for carcinogenic or mutagenic potential, or impairment of male fertility.
	Tdap (Boostrix)	BOOSTRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits and rats with BOOSTRIX had no effect on fertility.
	DTaP-IPV (Kinrix)	KINRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	DTaP-IPV (Quadracel)	Quadracel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-HepB-IPV (Pediarix)	PEDIARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 16 fertility.
	DTaP-IPV/Hib (Pentacel)	Pentacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-IPV-Hib-HepB (Vaxelis)	VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
*	Pneumococcal	

	PCV13 (Pprevnar13)	Prevnam 13 has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. In a study in rabbits, no vaccine-related effects were found regarding reproductive performance including female fertility
	PCV15 (Vaxneuvance)	VAXNEUVANCE has not been evaluated for carcinogenic or mutagenic potential or for impairment of male fertility in animals. VAXNEUVANCE administered to female rats had no effect on fertility
	PCV20 (Pprevnar20)	Prevnam 20 has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. Vaccination of female rabbits with Prevnam 20 had no effect on female fertility
	PPSV23 (Pneumovax 23)	Section 13 not included
*	Polio	
	Polio (Ipol)	Long-term studies in animals to evaluate carcinogenic potential or impairment of fertility have not been conducted.
	DTaP-IPV (Kinrix)	KINRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	DTaP-IPV (Quadracel)	Quadracel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-HepB-IPV (Pediarix)	PEDIARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 16 fertility.
	DTaP-IPV/Hib (Pentacel)	Pentacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-IPV-Hib-HepB (Vaxelis)	VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
*	Rabies	
	Rabies (Imovax Rabies)	Section 13 is not included.
	Rabies (RabAvert)	Long-term studies with RabAvert have not been conducted to assess the potential for carcinogenesis, mutagenesis, or impairment of fertility.
*	Rotavirus	
	RV1 (Rotarix)	ROTARIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.
	RV5 (RotaTeq)	RotaTeq has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility. 14 CL
*	RSV	
	RSV (Abrysvo)	ABRYSVO has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. A developmental toxicity study in female rabbits revealed no evidence of impaired female fertility after administration of a vaccine formulation containing two times the antigen content of a single human dose of ABRYSVO
	RSV (Arexvy)	AREXVY has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	RSV (Beyfortus)	Carcinogenesis, mutagenesis and reproductive toxicity studies have not been performed with BEYFORTUS.
*	Rubella	

	MMR (M-M-R II)	M-M-R II vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility
	MMR (Priorix)	PRIORIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	MMRV (ProQuad)	ProQuad has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility.
*	Shingles	
	RZV (Shingrix)	SHINGRIX has not been evaluated for its carcinogenic or mutagenic potential. Vaccination of female rats with SHINGRIX had no effect on fertility. In a male fertility study, rats were vaccinated with 0.1 mL of SHINGRIX (a single human dose is 16 0.5 mL) on 42, 28, and 14 days prior to mating. There were no effects on male fertility.
*	Smallpox	
	Vaccinia (ACAM2000):	Section 13 is not included
	Jynneos	JYNNEOS has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Developmental toxicity studies conducted in rats and rabbits vaccinated with JYNNEOS revealed no evidence of impaired female fertility
*	Tetanus	
	DTaP (Daptacel)	DAPTACEL has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP (Infanrix)	INFANRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of 14 fertility.
	Td (Tenivac)	TENIVAC has not been evaluated for carcinogenic or mutagenic potential or impairment of male fertility in animals. Vaccination of female rabbits with TENIVAC had no effects on fertility.
	Td (generic)	No studies have been performed with MassBiologics' TDVAX to evaluate carcinogenicity, mutagenic potential, or impairment of fertility.....PREGNANCY Animal reproduction studies have not been conducted with MassBiologics' TDVAX. It is also not known whether MassBiologics' TDVAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. MassBiologics' TDVAX should be given to a pregnant woman only if clearly needed....NURSING MOTHERS It is not known whether MassBiologics' TDVAX is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when MassBiologics' TDVAX is administered to a nursing woman.
	Tdap (Adacel)	Adacel has not been evaluated for carcinogenic or mutagenic potential, or impairment of male fertility.
	Tdap (Boostrix)	BOOSTRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits and rats with BOOSTRIX had no effect on fertility.
	DTaP-IPV (Kinrix)	KINRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	DTaP-IPV (Quadracel)	Quadracel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

	DTaP-HepB-IPV (Pediatrix)	PEDIARIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility.
	DTaP-IPV/Hib (Pentacel)	Pentacel has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
	DTaP-IPV-Hib-HepB (Vaxelis)	VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.
*	Tuberculosis	
	(BCG Vaccine)	BCG VACCINE has not been evaluated for carcinogenic, mutagenic potentials or impairment of fertility.
*	Typhoid Fever	
	Typhoid Oral (Vivotif)	Long-term studies in animals with Vivotif have not been performed to evaluate carcinogenic potential, mutagenic potential or impairment of fertility.
	Typhoid Polysaccharide (Typhim Vi)	Typhim Vi vaccine has not been evaluated for its carcinogenic potential, mutagenic potential or impairment of fertility.
*	Varicella	
	VAR (Varivax)	Section 13 is not included
	MMRV (ProQuad)	ProQuad has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility.
*	Yellow Fever	
	YF (YF-Vax)	YF-VAX has not been evaluated for its carcinogenic or mutagenic potential or its effect on fertility