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Mercury in Drug and Biologic Products

<http://www.fda.gov/cder/fdama/mercury300.htm>

The information in this list is derived from submissions made by manufacturers (manufacturers, repackers, relabelers, and distributors) in response to the agency's call-for-data notices of December 14, 1998 (63 FR 68775), April 29, 1999 (64 FR 23083) and February 3, 2003 (68 FR 5299), the agency's Drug Registration and Listing System, and other agency sources. Products submitted in response to any of the call-for-data notices are preceded by an asterisk (*) [in the first column of the table]. The mercury ingredients are abbreviated as TM for thimerosal, PMA for phenylmercuric acetate, PMN for phenylmercuric nitrate, MA for mercuric acetate, MN for mercuric nitrate, MB for merbromin, and MOY for mercuric oxide yellow. The list includes nonhomeopathic human and veterinary drug products and human biological products. Homeopathic drug products are not included because of the low amounts of mercury present in the products. The abbreviation NS under the % column means that the information was "not stated" in the agency's Drug Registration and Listing System.

Thimerosal content for [human] biological products can be found at [Thimerosal in Vaccines](http://www.fda.gov/cber/vaccine/thimerosal.htm) (<http://www.fda.gov/cber/vaccine/thimerosal.htm>) and [Mercury in Plasma-Derived Products](http://www.fda.gov/cber/vaccine/thimerosal.htm) (<http://www.fda.gov/cber/vaccine/thimerosal.htm>).

[Note that this does not include veterinary products. FDA was not required to include veterinary products in the report required by Congress in FDAMA 1997. Veterinary vaccines are under the jurisdiction of USDA Animal and Plant Health Inspection Service (APHIS); all other veterinary drugs are under the jurisdiction of USDHHS FDA Center for Veterinary Medicine.]

Manufacturer	Name of Product	Ingredient	%
Akorn Inc.	AK Spore Ophthalmic Solution	TM	.001
Akorn Inc.	AK Spore HC Ophthalmic Combo Drops	TM	NS
Akorn Inc.	Fluoracaine Ophthalmic Solution	TM	NS
Akorn Inc.	AK Spore HC Otic Suspension	TM	NS
* Alcon Laboratories	Profenal 1% Ophthalmic Solution	TM	.005
* Alcon Laboratories	Adsonbonac 2% Ophthalmic Solution	TM	.004
* Alcon Laboratories	Adsonbonac 5% Ophthalmic Solution	TM	.004
Allergan America	Ocufen Ophthalmic Solution	TM	.005
Allergan America	Poly Pred Ophthalmic Suspension	TM	.001
Allergan Inc.	Blephamide SOP Ophthalmic Ointment	PMA	.0008

Manufacturer	Name of Product	Ingredient	%
Allergan Inc.	Bleph-10 Ophthalmic Ointment 10%	PMA	.0008
Allergan Inc.	FML SOP Ophthalmic Ointment 0.1%	PMA	.0008
Allergan Inc.	Poly Pred Ophthalmic Suspension	TM	.001
Altaire Pharmaceuticals	Nasal Relief 12 Hour Spray	PMA	NS
American Assn. Retired Persons	Oxymetazoline Nasal Spray	PMA	.002
American International Chemical	Thimerosal (bulk chemical) (this company no longer sells thimerosal; telephone conversation May 3, 2005)	TM	100
American International Chemical	Thimerosal USP 97% (bulk chemical) (this company no longer sells thimerosal; telephone conversation May 3, 2005)	TM	97
American Pharmaceutical	12 Hour Nasal Solution	PMA	NS
Appletree Markets	Long Lasting Nasal Spray	PMA	NS
* Bausch & Lomb	Flurbiprofen Sodium Ophthalmic Solution	TM	.005
* Bausch & Lomb	Neomycin & Polymyxin B Sulfates & Gramicidin Ophthalmic Solution	TM	.001
* Bausch & Lomb	Neomycin & Polymyxin B Sulfates & Hydrocortisone Otic Suspension	TM	.01
* Bausch & Lomb	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution 10%/.23%	TM	.01
* Bristol-Myers Squibb	Fungizone Lotion	TM	.01
* Bristol-Myers Squibb	Fungizone Cream	TM	.01
C.O. Truxton Inc.	Bio-Cot Otic Suspension	TM	.01
C.O. Truxton Inc.	Decongest Nasal Spray	PMA	NS
Cheshire Pharmaceutical	Otocort Otic Suspension	TM	.01
Cheshire Pharmaceutical	Ocutricin Ophthalmic Solution	TM	.01

Manufacturer	Name of Product	Ingredient	%
Cheshire Pharmaceutical	Sulfapred Ophthalmic Solution	TM	NS
CVS	Nasal Spray Pump	PMA	NS
CVS Revco DS Inc.	12 Hour Decongestant Pump Nasal Spray	PMA	NS
Dolder Ltd. (Switzerland)	Thimerosal (bulk chemical)	TM	100
Dorex International Corp.	Long Acting Nasal Spray	PMA	.002
Drug Guild Distributors	Long Acting Nasal Spray Kalex LA	PMA	.002
DRX Pharmaceutical	Blephamide Ophthalmic Ointment	PMA	NS
DRX Pharmaceutical	Cortisporin Ophthalmic Suspension	TM	.001
DRX Pharmaceutical	Neomycin Polymyxin B Sulfates Hydrocortisone Ophthalmic Suspension	TM	NS
DRX Pharmaceutical	Neomycin Polymyxin B Hydrocortisone Otic Suspension	TM	.01
DRX Pharmaceutical	Neomycin Polymyxin B Gramicidin Ophthalmic Solution	TM	.01
DRX Pharmaceutical	Vasocidin Ophthalmic Solution	TM	NS
DRX Pharmaceutical	Colymycin S Otic Suspension	TM	.002
DRX Pharmaceutical	Pediotic Otic Suspension	TM	NS
Dysers Sal	Thimerosal (bulk chemical)	TM	NS
Family Independent Pharmacy	12 Hour Nasal Decongestant Spray	PMA	NS
Family Independent Pharmacy	Long Acting Nasal Spray	PMA	NS
Farm Fresh Inc.	Hemorrhoid Relief Ointment	PMN	.01
Fays Drug Services	12 Hour Nasal Spray Pump	PMA	NS
Federated Foods	Long Acting Nasal Spray	PMA	.002
Fleming Companies	12 Hour Nasal Spray	PMA	.002

Manufacturer	Name of Product	Ingredient	%
Foxmeyer Drug Co.	Nasal Spray Pump	PMA	NS
Global Source	Nasin Long Acting Nasal Spray	PMA	NS
Harco Drug	Mercurochrome Aqueous Solution	MB	2
Harris-Teeter	Oxymetazoline Nasal Spray	PMA	.002
Hi Tech Pharmacal Co.	Long Acting Nasal Spray	PMA	.002
Hudson Corp.	Nasal Spray Extended Relief	PMA	NS
Hurst Pharmaceutical	Duomycin-HC Otic Suspension	TM	.01
K and B Distributors	Mercurochrome Aqueous Solution	MB	2
* King Pharmaceuticals	Cortisporin Ophthalmic Suspension	TM	.001
* King Pharmaceuticals	Neosporin Ophthalmic Suspension	TM	.001
* King Pharmaceuticals	Viroptic Ophthalmic Solution	TM	.001
King Pharmaceuticals	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	NS
* King Pharmaceuticals	Pediotic Suspension	TM	.001
* King Pharmaceuticals	Cortisporin Otic Suspension	TM	.01
Kinray	Oxymetazoline Nasal Spray	PMA	.002
Laboratori Derivati	Adrenal Cortex Injection	TM	.01
Leader	12 Hour Nasal Spray	PMA	NS
Leader	Nasal Pump Spray	PMA	NS
Longs Drug Stores	Nasal Spray Pump	PMA	NS
LS Raw Materials Ltd. (Israel)	Mercurochrome NF 12 100% (bulk chemical)	MB	100
Major Pharmaceuticals	Cortomycin Ophthalmic Suspension	TM	NS
Major Pharmaceuticals	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution	TM	.01
Major Pharmaceuticals	Cortomycin Otic Suspension	TM	.01
Major Pharmaceuticals	Neocidin Ophthalmic Solution	TM	.01

Manufacturer	Name of Product	Ingredient	%
Martin Surgical Supply	Testosterone Injection Suspension 50 mg	TM	.008
Martin Surgical Supply	Testosterone Injection Suspension 100 mg	TM	NS
Mays Drug Stores	Hemorrhoid Relief Ointment	PMN	.01
Medalist Laboratories	Long Lasting Nasal Spray Pump	PMA	NS
Meyers Supply Inc.	Long Acting Nasal Spray	PMA	.002
Navresso	Long Acting Nasal Spray	PMA	NS
Omicron Quimica SA (Spain)	Thimerosal USP 97% (bulk chemical)	TM	97
Parade (Grocer's Supply)	Oxymetazoline Nasal Spray	PMA	.002
* Parkedale Pharmaceuticals	Coly-Mycin S Otic Suspension	TM	.002
Pay N Save Corp.	Decongestant Nasal Spray	PMA	NS
Pharmedix	Bleph 10 Ophthalmic Solution 10%	TM	.005
Pharmedix	Viroptic Ophthalmic Solution 1%	TM	.001
Pharmedix	Blephamide Ophthalmic Ointment	PMA	NS
Pharmedix	Triple Antibiotic Ophthalmic Solution	TM	.01
Pharmedix	Colymycin S Otic Solution	TM	.002
Pharmedix	Neo Poly with HC Otic Suspension	TM	.01
Physicians Total Care Inc.	Neomycin Polymyxin B Sulfates Hydrocortisone Ophthalmic Suspension	TM	NS
Physicians Total Care Inc.	Viroptic Ophthalmic Solution	TM	.001
Physicians Total Care Inc.	Cortisporin Ophthalmic Suspension	TM	.001
Physicians Total Care Inc.	Ocufen Ophthalmic Solution	TM	.0005
Physicians Total Care Inc.	Vasocidin Ophthalmic Solution	TM	NS

Manufacturer	Name of Product	Ingredient	%
Ping On Ointment Co. Ltd.	Ping On Topical Ointment	Mercury	NS
Prime Natural Health	12 Hour Nasal Spray	PMA	NS
Primedics Laboratories	Testosterone Injection Suspension 50 mg	TM	.008
Publix Inc.	Long Acting Nasal Spray	PMA	NS
Publix Supermarkets	Long Acting Decongestant Nasal Spray	PMA	NS
Qualitest Pharmaceuticals	Nasal Spray Solution	PMA	NS
Qualitest Pharmaceuticals	Antibiotic HC Otic Suspension	TM	NS
RDS Acquisition Corp.	12 Hour Nasal Spray	PMA	NS
Republic Drug Co.	12 Hour Nasal Spray	PMA	.002
* Schering-Plough Animal Health	Gentocin Durafilm Ophthalmic Solution (for dogs only)	PMN	.002
Scrivner, Inc.	Hemorrhoid Relief Ointment	PMN	.01
Sight Pharmaceuticals	Neomycin Polymyxin B Sulfates Hydrocortisone Otic Suspension	TM	NS
Sight Pharmaceuticals	Sulfacetamide Sodium & Prednisolone Sodium Phosphate Ophthalmic Solution	TM	.01
Spectrum Quality Products	Merbromin (bulk chemical)	MB	100
Spectrum Quality Products	Mercuric Oxide Yellow (bulk chemical)	MOY	100
Spectrum Quality Products	Thimerosal (bulk chemical)	TM	100
Spectrum Quality Products	Thimerosal (bulk chemical)	TM	100
Super Laboratories	Long Acting Nasal Spray	PMA	NS
* Taro Pharmaceuticals	Taro Nasal Decongestant Spray	PMA	.002
Teral Laboratories	Oticin HC Otic Suspension	TM	.01
Thames Pharmacal Co.	12 Hour Nasal Spray	PMA	NS

Manufacturer	Name of Product	Ingredient	%
Thrifty Payless Inc.	Nasal Spray Pump Formula	PMA	NS
Thrifty Payless Inc.	Decongestant Nasal Spray Pump	PMA	NS
United Research Labs	Antibiotic Ear Suspension	TM	.01
United Research Labs	Neomycin Polymyxin B Sulfates Gramicidin Ophthalmic Solution	TM	.01
US Ophthalmics	Fluorescein Sodium Ophthalmic Solution	TM	NS
US Ophthalmics	Sulf-10 Ophthalmic Solution	TM	NS
US Ophthalmics	Vasocidin Ophthalmic Solution	TM	NS
US Ophthalmics	Phenylephrine HC1 Ophthalmic Solution 10%	TM	NS
USCO Logistics	Procofen Ophthalmic Solution	TM	.005
USCO Logistics	Profenal Ophthalmic Solution	TM	.005
VEDCO Inc.	Tribiotic Ophthalmic Solution	TM	NS
Waldbaum Inc.	Hemorrhoidal Ointment	MN	NS
Weeks and Leo Co. Inc.	Long Acting Nasal Spray Solution	PMA	.002
* Whitehall-Robins	Dristan 12-Hour Nasal Spray	TM	.002

Date created: August 5, 2003; updated September 14, 2004

Mercury in Plasma-Derived Products (updated 9/9/2004)
<http://www.fda.gov/cber/blood/mercplasma.htm>

Mercury in Plasma-Derived Products

The EPA has raised concerns regarding mercury exposure. These concerns have been in the context of chronic exposure to methyl mercury in milligram amounts. In contrast, blood plasma-derived products (except anti-venoms) containing ethyl mercury are usually given as one or two injections. Furthermore, the ethyl mercury content of these products is in the form of a preservative, thimerosal, which breaks down to form ethyl mercury in microgram amounts.

In the past, plasma-derived products made in multiple-use vials, e.g. Immune Globulin (Human), used for Hepatitis A prophylaxis, contained a preservative, such as ethyl mercury-containing thimerosal, to avoid contamination. This type of multi-dose presentation has been discontinued for all licensed plasma derivative products.

Rho (D) Immune Globulin (Human) products -

RhoGAM, Ortho Clinical Diagnostics, Inc
BayRho, Bayer Corporation
WinRho, Cangene Corporation

RhoGAM, Ortho Clinical Diagnostics, Inc [licensed 1968]

On April 16, 2001, Ortho Clinical Diagnostics was approved by FDA to produce RhoGAM without thimerosal, and at that time, Ortho agreed to distribute only thimerosal-free product to the US market. The product has a 2-year dating period, so there is no longer any RhoGAM that contains thimerosal that is still in-date.

The following information does not apply to any RhoGAM product currently on the market, but is provided to allow interested individuals to estimate the ethyl mercury content of any RhoGAM treatment that might have been administered in the past, when the thimerosal preservative was still a component of that product.

RhoGAM is manufactured in two doses only: the standard dose of "300 micrograms" of anti-D, and the micro-dose of "50 micrograms" of anti-D. The fill volume for both the standard dose and micro-dose products is typically between 0.6 and 0.8 mL. Preservative-containing RhoGAM contained thimerosal at 0.003%, or 30 micrograms per milliliter. Thimerosal is about 50% ethyl mercury by weight. Hence, a patient who had received a dose of RhoGAM (0.7 ml on average) would have received 10.5 micrograms of ethyl mercury.

There are three indications for which an Rh-negative pregnant woman would receive a significantly larger dose of RhoGAM: a fetal-maternal hemorrhage early in the pregnancy, a fetal-maternal hemorrhage greater than 15 ml of Rh+ red cells, and an Rh+ transfusion. In the first case, a single 300 microgram dose of RhoGAM, is recommended at 12-week intervals. For the second two indications, a procedure exists by which to determine the dose of RhoGAM required, based on the amount of Rho+ red cells in the maternal circulation: the Kleihauer-Betke elution test (see the AABB Technical Manual, 13th ed., pp. 507-8.) The total dose of mercury that would have been received can be calculated by multiplying the number of RhoGAM syringes administered by 10.5 micrograms.

BayRho, Bayer Corporation [licensed 1971]

The Bayer Corporation makes a Rho (D) Immune Globulin product (BayRho) which in the past contained thimerosal; this product has been manufactured without preservative since 1996, so that no in-date BayRho contains thimerosal. Regarding the previously distributed product, the volume of a single dose of the Bayer product was approximately 0.7 ml. The thimerosal concentration was 0.01%, so the total mercury in a single dose would have been approximately 35 micrograms of ethyl mercury.

WinRho SD, Cangene Corporation [licensed 1996]

The Cangene Corporation makes a freeze-dried Rho (D) Immune Globulin Intravenous (WinRho SD); this product has never contained a preservative.

Other Products

In addition, four other plasma-derived products remain on the market that contain or contained ethyl mercury preservatives. They are as follows:

1. Antivenin (Crotalidae) Polyvalent (Equine); Pit viper snake antivenom, Wyeth Pharmaceuticals Inc
2. Antivenin (Micrurus fulvius); Coral snake antivenom (Equine), Wyeth Pharmaceuticals Inc
3. Crotalidae Polyvalent Immune Fab (Ovine); Pit viper snake antivenom, Protherics Inc
4. Antivenin (Lacrodectus mactans); Black Widow spider antivenom (Equine), Merck & Co, Inc

**Pit Viper [Antivenin (Crotalidae) Polyvalent, licensed 1954] and
Coral Snake [Antivenin (Micrurus fulvius), licensed 1967] antivenoms by Wyeth**

These products are equine antisera. They are in lyophilized form and when reconstituted contain 0.005% thimerosal (50 micrograms per milliliter). The diluent, WFI, contains the preservative phenylmercuric nitrate at 0.001% concentration (10 micrograms per milliliter). A patient bitten by a snake may receive 15 or more vials (doses of 50 vials have been reported) if the envenomization is severe. A 15 vial dose of this antivenom would contain 4.7 milligrams of mercury.

Wyeth plans to discontinue these products; however, the current supply will last several years, until each lot reaches its expiration date. Rattlesnake bites are dangerous and can cause serious morbidity or mortality. In the interest of the public health these products need to be available until sufficient ethyl mercury-free product can be provided to the public.

**Pit Viper antivenom [Crotalidae Polyvalent Immune Fab (Ovine) licensed October 2000,
Protherics]**

Mercury is not added to the final product in the form of a preservative, but thimerosal is used to assure that the chromatography columns used in the manufacturing of this product do not become bacterially contaminated with repeated use. The product was approved but the ethyl mercury content was limited to not more than 104.5 micrograms ethyl mercury per vial, with a recommended maximum dose of 18 vials. A patient receiving this product would receive about 1.88 milligrams of mercury.

Black Widow Spider antivenom [Antivenin (Lacrodectus mactans), licensed 1936, Merck]

This product is an equine antiserum. The reconstituted product contains 0.1 milligrams of mercury per milliliter, so that the maximum 2-vial dose would contain 0.25 milligrams of mercury. Black Widow Spider bites can be lethal, and the dose is limited to not more than two vials. It has been determined that removal of the product from the market by the FDA would not be in the best interests of public health.

STAFF DRAFT Thimerosal and Mercury Content of Vaccines and Related Products Distributed in the United States; March 30, 2005

Vaccine/Biologic	Brand name	Manufacturer	Type	How supplied	Mercury content (MNOEA review of Product Inserts)	‡
Diphtheria, Tetanus, acellular Pertussis	Infanrix	GlaxoSmithKline	Inactivated	single-dose vial or syringe	No Thimerosal	3
Diphtheria, Tetanus, acellular Pertussis	Tripedia	Aventis Pasteur	Inactivated	single-dose vial	The 1 dose vial of vaccine is formulated without preservatives but contains a residual amount of thimerosal [(mercury derivative), ($\leq 0.3 \mu\text{g}$ mercury/dose)] from the manufacturing process.	2
Diphtheria, Tetanus, acellular Pertussis	Tripedia	Aventis Pasteur	Inactivated	Multi dose vial (7.5 ml)	The multidose (7.5 mL) vial of vaccine contains the preservative thimerosal [(mercury derivative), $25 \mu\text{g}$ mercury/dose].	1
Diphtheria, Tetanus, acellular Pertussis	Daptacel	Aventis Pasteur	Inactivated	single-dose vial	Thimerosal-free 3.3 mg (0.6% v/v) 2-phenoxyethanol as preservative	3
Diphtheria, Tetanus, acellular Pertussis + Hib	TriHIBit (Tripedia+ActHIB)	Aventis Pasteur	Inactivated	single-dose vial	Same as Tripedia. Contains $\leq 0.3 \mu\text{g}$ mercury/dose or $25 \mu\text{g}$ mercury/dose.	2 1
Diphtheria, Tetanus, acellular Pertussis + Hep B + IPV	Pediarix	GlaxoSmithKline	Inactivated	single-dose vial or syringe	Thimerosal used in manufacturing process. Contains $<12.5 \text{ ng}$ mercury per dose. (Mfr states merc content below analytical limit)	2
Diphtheria, Tetanus (DT; pediatric <7 yrs)	generic	Aventis Pasteur	Inactivated	10-dose vial	The multidose (5 mL) vial of vaccine contains the preservative thimerosal ($25 \mu\text{g}$ Hg/0.5 mL dose).	1
Diphtheria, Tetanus (DT; ped <7 yrs, preservative-free)	generic	Aventis Pasteur	Inactivated	single-dose vial	Residual amount of thimerosal from the mfg process ($\leq 0.3 \mu\text{g}$ Hg/0.5 mL dose).	2
Tetanus, diphtheria, adsorbed (Td; >7 yrs)	generic	Aventis Pasteur	Inactivated	single-dose syringe and 10-dose vial	Thimerosal (a mercury derivative) 1:10,000 is added as a preservative. (0.01%)	1
Tetanus, diphtheria, adsorbed (Td; >7 yrs)	generic	Mass. Biologic Labs1	Inactivated	15-dose vial	Thimerosal 1:30,000, approx. 8.26 mcg per 0.5 mL dose	1
Tetanus toxoid (TT; >7 yrs), adsorbed	generic	Aventis Pasteur	Inactivated	10-dose vial	Thimerosal (a mercury derivative) at a final concentration of 1:10,000. (0.01%)	1
Tetanus toxoid (TT; adult booster use only)	generic	Aventis Pasteur	Inactivated	15-dose vial	Each dose contains the preservative thimerosal [(mercury derivative), $25 \mu\text{g}$ mercury/dose].	1
Tetanus immune globulin (TIG)	BayTet	Bayer	Human immunoglobulin	single-dose syringe	No preservative	3
<i>Haemophilus influenzae</i> type b (PRP-T)	ActHIB	Aventis Pasteur	Inactivated	single-dose vial	ActHIB contains no thimerosal, administered by itself....	3
					Administered with AvP DTP.....	1
					Administered with TriPedia single dose.....	2
					Administered with TriPedia multidose (licensed use?)....	1
					Administered with Daptacel (licensed use?).....	3
<i>Haemophilus influenzae</i> type b (HbOC)	HibTITER	Wyeth	Inactivated	single-dose vial	Apparently no preservative or thimerosal	3
<i>Haemophilus influenzae</i> type b (PRP-OMP)	PedvaxHIB	Merck	Inactivated	single-dose vial	No thimerosal	3
<i>Haemophilus influenzae</i> type b (PRP-OMP) + Hep B	Comvax	Merck	Inactivated	single-dose vial	No preservative, no thimerosal	3
Hepatitis A: ped/adol & adult formulations	Havrix	GlaxoSmithKline	Inactivated	single-dose vial or syringe	No thimerosal, 0.5% (w/v) of 2-phenoxyethanol as a preservative.	3

Vaccine/Biologic	Brand name	Manufacturer	Type	How supplied	Mercury content (MNOEA review of Product Inserts)	‡
Hepatitis A: ped/adol & adult formulations	Vaqta	Merck	Inactivated	single-dose vial or syringe	No thimerosal, no preservative.	3
Hepatitis A immune globulin	BayGam	Bayer	Human immunoglobulin	2 mL and 10 mL vials	“No preservative”	3
Hepatitis B: ped/adol & adult formulations	Engerix-B	GlaxoSmithKline	Inactivated	single-dose vial or syringe	0.5 mL ped dose contains < 0.5 mcg mercury 1.0 mL adult dose contains <1.0 mcg mercury (residual thimerosal from mfg process)	2
Hepatitis B: ped/adol & adult* formulations	Recombivax HB	Merck	Inactivated	single-dose vial*	No thimerosal, no preservative.	3
Hepatitis B: dialysis* formulation	Recombivax HB	Merck	Inactivated	single-dose vial*	No thimerosal, no preservative.	3
Hepatitis B immune globulin (HBIG)	BayHep B	Bayer	Human immunoglobulin	1 mL syringe, 1 mL or 5 mL vial	No thimerosal, no preservative.	3
Hepatitis B immune globulin (HBIG): ped formulation	BayHep B	Bayer	Human immunoglobulin	single-dose 0.5 mL neonatal syringe	No thimerosal, no preservative.	3
Hepatitis B immune globulin (HBIG)	Nabi-HB	Nabi	Human immunoglobulin	single-dose vial	No thimerosal, no preservative.	3
Hepatitis A & B: adult formulation	Twinrix	GlaxoSmithKline	Inactivated	single-dose vial or syringe	1.0 mL dose contains residual amount of thimerosal (<1 mcg mercury) from the mfg process	2
Measles, Mumps, Rubella (MMR)	M-M-R II	Merck	Live attenuated	single-dose vial	No preservative, no thimerosal	3
Measles	Attenuvax	Merck	Live attenuated	single-dose vial	No preservative, no thimerosal	3
Mumps	Mumpsvax	Merck	Live attenuated	single-dose vial	No preservative, no thimerosal	3
Rubella	Meruvax II	Merck	Live attenuated	single-dose vial	No preservative, no thimerosal	3
Meningococcal polysaccharide (A/C/Y/W-135)	Menomune	Aventis Pasteur	Inactivated	single-dose vial	Single dose vial contains no thimerosal	3
Meningococcal polysaccharide (A/C/Y/W-135)	Menomune	Aventis Pasteur	Inactivated	10-dose vial	Multi-dose vial contains ~0.01% thimerosal as preservative.	1
Pneumococcal conjugate, 7-valent	Prevnar	Wyeth	Inactivated	single-dose vial	Apparently no preservative	3
Pneumococcal polysaccharide, 23-valent	Pneumovax 23	Merck	Inactivated	single-dose vial or 5-dose vial	No thimerosal. Each 0.5 mL dose of vaccine contains 0.25% phenol as a preservative.	3
Polio (IPV)	IPOL	Aventis Pasteur	Inactivated	single-dose syringe and 10-dose vial	No thimerosal. 0.5% 2-phenoxyethanol and max 0.02% formaldehyde per dose as preservatives	3
Varicella	Varivax	Merck	Live attenuated	single-dose vial	No preservative, no thimerosal	3
Varicella-zoster immune globulin (VZIG)	generic	Mass. Biologic Labs2	Human immunoglobulin	125-unit and 625-unit vials (IV)	No preservative, no thimerosal	3
Anthrax, adsorbed	BioThrax	BioPort	Inactivated	multi-dose vial	No thimerosal.	3
Japanese encephalitis	JE-VAX	Aventis Pasteur	Inactivated	single- and 10-dose vial	Thimerosal preservative 0.007%	1
Rabies	Imovax	Aventis Pasteur	Inactivated	single-dose vial	No preservative, no thimerosal	3
Rabies	RabAvert	Chiron	Inactivated	single-dose vial	No preservative, no thimerosal	3
Rabies immune globulin (RIG)	Imogam Rabies-HT	Aventis Pasteur	Human immunoglobulin	2 mL and 10 mL vials	No preservative, no thimerosal	3
Rabies immune globulin (RIG)	BayRab	Bayer	Human immunoglobulin	2 mL and 10 mL vials	No preservative, no thimerosal	3
Typhoid Vi polysaccharide	Typhim Vi	Aventis Pasteur	Inactivated	single-dose syringe and 20-dose vial	No thimerosal. Phenol, 0.25%, is added as a preservative.	3
Typhoid, live oral Ty21a	Vivotif	Berna	Live attenuated	4-capsule package	No thimerosal	3
Yellow fever	YF-Vax	Aventis Pasteur	Live attenuated	single- and 5-dose vial	No preservative, no thimerosal.	3

Vaccine/Biologic	Brand name	Manufacturer	Type	How supplied	Mercury content (MNOEA review of Product Inserts)	‡
Influenza Vaccines						
Influenza 2002-2003						
Influenza	FluShield	Wyeth Ayerst	Inactivated	5 ml 10-dose vial	Contains thimerosal, 0.01% or 25 µg mercury per 0.5 mL dose as a preservative	1
Influenza (TIV)	Fluzone	Aventis Pasteur	In activated	0.5 ml single dose syringe and 5 ml 10-dose vial	25 µg mercury/0.5 mL dose as a preservative	1
Influenza: (TIV; ped 6-35 mos; preservative-free)	Fluzone	Aventis Pasteur	Inactivated	single-dose syringe (0.25 & 0.5 mL)	≤0.5 µg Hg/0.25 mL dose ≤1.0 µg Hg/0.5 mL dose	2
Influenza 2003-2004						
Influenza (live attenuated influenza vaccine [LAIV])	FluMist	MedImmune	Live, intranasal	10 single-use sprayers	No thimerosal, no preservatives	3
Influenza (trivalent inactivated; influenza vaccine [TIV])	Fluvirin	Chiron/Evans	Inactivated	single dose syringe and 10-dose vial	“Thimerosal 0.01% (mercury derivative, 24.5 mcg per 0.5 mL dose) is added as a preservative.”	1
Influenza (TIV)	Fluzone	Aventis Pasteur	Inactivated	0.5 mL single-dose syringe and 5 mL 10-dose vial	25 µg mercury/0.5 mL dose as preservative	1
Influenza (TIV; ped 6-35 mos; preservative-free)	Fluzone	Aventis Pasteur	Inactivated	single-dose syringe (0.25 mL)	≤0.5 µg Hg/0.25 mL dose	2
Influenza 2004-2005						
Influenza (live attenuated influenza vaccine [LAIV])	FluMist	MedImmune	Live, intranasal	10 single-use sprayers	No thimerosal, no preservatives	3
Influenza (trivalent inactivated; influenza vaccine [TIV], preservative free) Withheld from market**	Fluvirin	Chiron/Evans	Inactivated	single-dose syringe	“Thimerosal (mercury derivative, +0.98 mcg per 0.5 mL dose) is used in manufacturing of preservative free unit dose but is reduced by the purification process to trace [residual] amounts.”	2
Influenza (trivalent inactivated; influenza vaccine [TIV]) Withheld from market**	Fluvirin	Chiron/Evans	Inactivated	10-dose vial	“Thimerosal 0.01% (mercury derivative, 24.5 mcg per 0.5 mL dose) is added as a preservative.”	1
Influenza (TIV)	Fluzone	Aventis Pasteur	Inactivated	0.25 ml single dose/6-35 mo. 0.5 mL single-dose syringe and 5 mL 10-dose vial	12.5 µg mercury/0.25 mL dose as preservative 25 µg mercury/0.5 mL dose as preservative “	1 1 1
Influenza: (TIV; ped 6-35 mos; preservative-free)	Fluzone	Aventis Pasteur	Inactivated	single-dose syringe (0.25 mL)	≤0.5 µg Hg/0.25 mL dose	2

1Distributed by General Injectables & Vaccines, Inc. (800) 270-2273

2Distributed by FFF Enterprises (800) 843-7477

*As of March 21, 2005, FDA CBER website (<http://www.fda.gov/cber/vaccine/thimerosal.htm>) states that Merck manufactures multi-dose vials of adult/dialysis Recombivax HB containing 0.005% thimerosal (25 mcg/1.0 mL dose) as preservative.

** As of March 21, 2005, FDA CBER website does not state that this vaccine was withheld from the market for the entire 2004-2005 influenza season.

This product listing is no older than March 2004. Product Insert dates vary.

‡ Key to Exposure and Pollution Prevention Categorization for vaccines and biologic products for thimerosal/mercury content

Category:	Thimerosal/mercury content of Vaccine	Mercury Exposure to vaccinated individual	Pollution Prevention
1	“Status Quo” Thimerosal content, most vaccines contain 12.5 mcg mercury per pediatric dose and 25 mcg mercury per adult dose as preservative; JE-Vax contains ~18 mcg/dose and MBL Td vaccine contains ~8.3 mcg mercury per dose.	Exposure to vaccinated individual is unchanged since 1999 AAP-PHS Statement on removal of mercury from vaccines.	No Pollution Prevention. Mercury demand and inputs to manufacturing continue at same level. Manufacturing wastes contain inorganic and organic mercury. Ongoing worker exposure or risk of exposure.
2	“Trace” or Residual Thimerosal content, ≤ 0.5 mcg mercury per pediatric dose or ≤ 1.0 mcg mercury per adult dose, as residual from manufacturing process. Some chance that vaccine will contain higher mercury level due to manufacturing variations.	Significantly reduced exposure to vaccinated individual, mercury content approx 1.2% to 5% of “Status Quo” vaccine.	Minimal Pollution Prevention. Mercury demand and inputs to manufacturing continue at same level. Overall demand may be lower due to reduced thimerosal content of final product. Manufacturing wastes contain inorganic and organic mercury. Waste generation may be greater since some mfrs state that they are extracting thimerosal from the vaccine. Ongoing worker exposure or risk of exposure.
3	Zero Thimerosal and Mercury Content. No chance that vaccine will contain higher level of mercury than disclosed.	Zero mercury exposure to vaccinated individual.	Pollution Prevention fully in place. No mercury demand, manufacturing inputs and wastes are free of mercury. No worker exposure.

Vaccine Company Contact Information

Aventis Pasteur Inc. (www.us.aventispasteur.com) (800) 822-2463
 Bayer Corporation (www.bayerbiologicalsusa.com) (800) 288-8370
 Berna Products Corporation (www.bernaproducts.com) (800) 533-5899
 BioPort Corporation (www.bioport.com) (877) 246-8472
 Chiron Corporation:
 - for influenza vaccine: (www.chiron.com) (800) 200-4278
 - for rabies vaccine: (www.rabavert.com or www.chiron.com) (800) 244-7668
 GlaxoSmithKline (www.gskvaccines.com) (866) 475-8222
 Mass. Biological Labs (617) 983-6400
 MedImmune Vaccines, Inc. (www.medimmune.com) (800) 358-7443
 Merck & Co., Inc. (www.merckvaccines.com) (800) 637-2579
 Nabi Biopharmaceuticals (www.nabi.com) (800) 327-7106
 Wyeth Vaccines (www.vaccineworld.com) (800) 572-8221

Table 1. Thimerosal Content of the Routinely Recommended Pediatric Vaccines

Vaccine	Tradename (Manufacturer)*	Thimerosal Status Concentration** (Mercury)	Approval Date for Thimerosal Free or Thimerosal / Preservative Free (Trace Thimerosal)*** Formulation
DTaP	Infanrix (GSK)	Free	Never contained Thimerosal
	Daptacel (AP)	Free	Never contained Thimerosal
	Tripedia (AP)	Trace ($\leq 0.3 \mu\text{g Hg}/0.5\text{mL dose}$)	03/07/01
DTaP-HepB-IPV	Pediarix (GSK)	Trace ($< 0.0125 \mu\text{g Hg}/0.5\text{mL dose}$)	Never contained more than a Trace of Thimerosal
Pneumococcal conjugate	Prevnar (WL)	Free	Never contained Thimerosal
Inactivated Poliovirus	IPOL (AP)	Free	Never contained Thimerosal
Varicella (chicken pox)	Varivax (M)	Free	Never contained Thimerosal
Mumps, measles, and rubella	M-M-R-II (M)	Free	Never contained Thimerosal
Hepatitis B	Recombivax HB (M)	Free	08/27/99
	Engerix B (GSK)	Trace ($< 0.5 \mu\text{g Hg}/0.5\text{mL dose}$)	03/28/00

Table 1. Thimerosal Content of the Routinely Recommended Pediatric Vaccines (continued)

Vaccine	Tradename (Manufacturer)*	Thimerosal Status Concentration** (Mercury)	Approval Date for Thimerosal Free or Thimerosal / Preservative Free (Trace Thimerosal)*** Formulation
Haemophilus influenzae type b conjugate (Hib)	ActHIB (AP)/ OmniHIB (GSK)	Free	Never contained Thimerosal
	PedvaxHIB (M)	Free	08/99
	HibTITER, single dose (WL) ¹	Free	Never contained Thimerosal
Hib/Hepatitis B combination	Comvax (M)	Free	Never contained Thimerosal
Influenza	Fluzone (AP)	0.01% (12.5 µg/0.25 mL dose, 25 µg/0.5 mL dose) ²	
	Fluzone (AP) (Preservative Free)	Trace (≤0.5 µg/0.25mL dose) ²	09/04/02
	Fluvirin (Chiron/Evans)	0.01% (25 µg/0.5 mL dose)	
	Fluvirin (Chiron/Evans) (Preservative Free)	Trace (<1µg Hg/0.5mL dose)	09/28/01
Influenza, live	FluMist ³ (MedImmune)	Free	Never contained Thimerosal

* Manufacturer abbreviations:

GSK = GlaxoSmithKline; WL = Wyeth Lederle; AP = Aventis Pasteur; M = Merck.

** Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 mL dose or 25 µg of Hg per 0.5 mL dose.

*** The term "trace" has been taken in this context to mean 1 microgram of mercury per dose or less. ("Trace" actually means "residual" since thimerosal is intentionally added as part of the vaccine manufacturing process.)

1. HibTiITER was also manufactured in thimerosal-preservative containing multidose vials but these were no longer available after 2002.
2. Children 6 months old to less than 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL; children 3 years of age and older receive 0.5 mL.
3. FluMist is not indicated for children less than 5 years of age.

Table 2: Preservatives Used in U.S. Licensed Vaccines

Preservative	Vaccine Examples (Tradename; Manufacturer*)
Thimerosal	DT Td (several) TT (several) Influenza (several)
2-phenoxyethanol and formaldehyde	IPV (IPOL; AP) DTaP (Daptacel; AP)
Phenol	Typhoid Vi Polysaccharide (Typhim Vi; AP) Pneumococcal Polysaccharide (Pneumovax 23; M)
Benzethonium chloride (Phemerol)	Anthrax (B)
2-phenoxyethanol	DTaP (Infanrix; GSK) Hepatitis A (Havrix; GSK) Hepatitis A/Hepatitis B (Twinrix; GSK)

*Manufacturer abbreviations:

GSK = Glaxo SmithKline; WL = Wyeth Lederle; AP = Aventis Pasteur; M = Merck; B=Bioport.

Table 3: Thimerosal and Expanded List of Vaccines

Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines				
Vaccine	Trade Name	Manufacturer	Thimerosal Concentration¹	Mercury
Anthrax	Anthrax vaccine	BioPort Corporation	0	0
DTaP	Tripedia ²	Aventis Pasteur, Inc.	< 0.0012%	0.3 µg/0.5 mL dose
	Infanrix	GlaxoSmithKline	0	0
	Daptacel	Aventis Pasteur, Ltd.	0	0
DTaP-HepB-IPV	Pediarix	GlaxoSmithKline	< 0.000005%	< 0.0125 µg/0.5 mL dose
DT	No Trade Name	Aventis Pasteur, Inc.	< 0.00012% (single dose) 0.01% (multi-dose)	< 0.3 µg/0.5mL dose 25 µg/0.5mL dose
		Aventis Pasteur, Ltd.	0.01%	25 µg/0.5 mL dose
Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL dose
	Decavac	Aventis Pasteur Inc.	<=0.00012%	0.3 µg mercury/ 0.5 ml dose
Td	No Trade Name	Aventis Pasteur, Ltd	0	0
TT	No Trade Name	Aventis Pasteur Inc.	0.01%	25 µg/0.5 mL dose
Hib	ActHIB/OmniHIB ³	Aventis Pasteur, SA	0	0
	HibTITER	Wyeth-Lederle	0	0
	PedvaxHIB liquid	Merck	0	0
Hib/HepB	COMVAX ⁴	Merck	0	0
Hepatitis B	Engerix-B	GlaxoSmithKline	< 0.0002%	< 0.5 µg/0.5 mL dose
	Recombivax HB ⁵	Merck	See footnote	See footnote
	Pediatric/adolescent		0	0
	Adult (adolescent)		0	0
	Adult (adolescent) ⁵		0.005%	25 µg/1.0 mL dose
Dialysis ⁵	0.005%		25 µg/1.0 mL dose	
Hepatitis A	Havrix	GlaxoSmithKline	0	0
	Vaqta	Merck	0	0

Table 3: Thimerosal and Expanded List of Vaccines (continued)

Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines				
Vaccine	Trade Name	Manufacturer	Thimerosal Concentration ¹	Mercury
HepA/HepB	Twinrix	GlaxoSmithKline	< 0.0002%	< 1 µg/1mL dose
IPV	IPOL	Aventis Pasteur, SA	0	0
	Poliovax	Aventis Pasteur, Ltd.	0	0
Influenza (2004-2005) <i>Chiron/Evans Fluvirin withheld from market</i>	Fluzone ⁶	Aventis Pasteur, Inc.	0.01%	25 µg/0.5 mL dose
	Fluvirin	Chiron/Evans	0.01%	25 µg/0.5 ml dose
	Fluzone (Preservative Free)	Aventis Pasteur, Inc.	≤ 0.0004%	≤ 0.5 µg/0.25 mL dose
	Fluvirin (Preservative Free)	Chiron/Evans	< 0.0004%	< 1 µg/0.5 mL dose
Influenza, live	FluMist	MedImmune	0	0
Japanese Encephalitis ⁷	JE-VAX	BIKEN	0.007%	35 µg/1.0mL dose 17.5 µg/0.5 mL dose
MMR	MMR-II	Merck	0	0
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Aventis Pasteur, Inc.	0.01% (multidose)	25 µg/0.5 dose
			0 (single dose)	0
Pneumococcal	Prevnar (Pneumo Conjugate)	Lederle Laboratories	0	0
	Pneumovax 23	Merck	0	0
Rabies	IMOVAX	Aventis Pasteur, SA	0	0
	Rabavert	Chiron Behring	0	0
Typhoid Fever	Typhim Vi	Aventis Pasteur, SA	0	0
	Typhoid Ty21a	Berna Biotech, Ltd	0	0
Varicella	Varivax	Merck	0	0
Yellow Fever	Y-F-Vax	Aventis Pasteur, Inc.	0	0

Table Footnotes

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 ml dose or 25 µg of Hg per 0.5 ml dose.
2. Aventis Pasteur's Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. OmniHIB is manufactured by Aventis Pasteur but distributed by GlaxoSmithKline.
4. COMVAX is not licensed for use under 6 weeks of age because of decreased response to the Hib component.
5. Merck's Hepatitis B vaccine for adults(adolescents) is available in both preservative-free and thimerosal-containing presentations. [Current Product Inserts state that only mercury free Recombivax is available.]
6. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
7. JE-VAX is manufactured by BIKEN and distributed by Aventis Pasteur. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).

Quantities of Hg in Waste (in pounds) for facilities in Chemicals (SIC 28) for U.S. 2002

Row #	Facility	State	SICs reported to TRI	Recycled On-site	Recycled Off-site	Quantity Disposed or Otherwise Released
51	ALBEMARLE CORP	SC	2834, 2869	0.00	68.00	0.00
60	PHARMACIA & UPJOHN CO	MI	2834	0.00	20.00	30.00
70	AVENTIS PASTEUR INC	PA	2834	0.00	24.90	9.59
81	EMD CHEMICALS INC	NJ	2835	0.00	0.00	23.55
97	CLINTON LABS.	IN	2833, 2879	0.00	0.05	12.90
102	PFIZER INC	NE	2834, 2836	0.00	2.80	7.00
104	MALLINCKRODT INC	MO	2833, 2835	0.00	0.00	8.80
108	ABBOTT LABORATORIES ABBOTT PARK FACILITY	IL	2833, 2834, 2835	0.00	0.00	7.00
109	MERIAL LTD	GA	2836	0.00	1.00	5.00
111	ORTHO CLINICAL DIAGNOSTICS INC.	NJ	2835	0.00	4.94	0.44
112	FORT DODGE ANIMAL HEALTH CHARLES CITY	IA	2834, 2836	0.00	0.00	5.25
114	NOVARTIS ANIMAL VACCINES INC.	IA	2836	0.00	0.00	4.40
118	FORT DODGE ANIMAL HEALTH - MAIN PLANT	IA	2834, 2836	0.00	0.00	3.70
119	BOEHRINGER INGELHEIM VETMEDICA INC	MO	2834, 2836	0.00	1.05	2.05
127	INTERVET INC.	DE	2836	0.00	1.43	0.35
143	PFIZER PHARMACEUTICAL LLC-ARECIBO	PR	2834	0.00	0.03	0.22
145	INTERVET INC.	IA	2836	0.00	0.00	0.22
148	ALPHA TEC SYSTEMS INC	WA	2835	0.00	0.00	0.11
174	SPECTRUM LABORATORY PRODUCTS (NEW JERSEY)	NJ	2819, 2833, 2869, 2899	0.00	0.00	0.00
175	SPECTRUM LABORATORY PRODUCTS INC	CA	2819, 2833, 2869, 2899	0.00	0.00	0.00
178	AMERICAN MASTER*TECH SCIENTIFIC INC.	CA	2835	0.00	0.00	0.00
					124.20	120.58

Total Production-related Waste Managed	website info
68.00	???
50.00	
34.49	
23.55	
12.95	
9.80	
8.80	
7.00	
6.00	
5.38	
5.25	
4.40	
3.70	
3.10	
1.79	
0.25	
0.22	
0.11	
0.00	
0.00	

Typical Decontamination and Disposal Processes Biomedical Facility Decommissioning Guidance

