

PharmEcology[®] Provides Disposal Guidelines for the 2023-2024 Flu Season

PharmEcology Services, a division of WM Sustainability Services, is pleased to publish a summary of the proper flu vaccine disposal guidelines for the 2023-2024 flu season as a public service to the healthcare community. Please also see additional information regarding this year’s vaccines following the table below.

Flu vaccine summary table:

The table below summarizes the waste categorizations of the specific products available this season. Applying EPA’s federal regulations to the flu vaccines, the vaccines meet the toxicity characteristic when the concentration of mercury is equal to or greater than 0.2mg/liter as a result of performing a test known as the toxicity characteristic leaching procedure (TCLP).

While we do not have results for such tests for vaccines, a calculation of the concentration of mercury in vaccines in which thimerosal is present as a preservative would cause the waste vaccine to fail the TCLP. Unless a manufacturer provides actual TCLP data indicating the mercury level to be below 0.2mg/liter or a healthcare facility has the test performed and the waste does not fail the TCLP, any vaccine waste containing thimerosal as a preservative should be managed as a toxic hazardous waste. As a result, all full or partially used multi-dose vials of the seasonal flu vaccine should be disposed of as federally hazardous waste, waste code D009 for mercury.

Trade name	Manufacturer	NDC	Size	Mercury content mcg/0.5ml (in the form of thimerosal preservative)	Categorization	Date of published package insert
Afluria Quadrivalent ¹	Seqirus	Ten single dose prefilled syringes (NDC 33332-323-04) Carton of 0.5 mL single-dose syringes (NDC 33332-323-03)	0.5 mL single dose prefilled syringes, without needles	No preservatives	Non-hazardous	2023

¹ <https://www.fda.gov/media/117022/download>

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Afluria Quadrivalent	Seqirus	5 mL multi-dose vial (NDC 33332-423-11) Carton of 5 mL vials, which contains ten 0.5 mL doses (NDC 33332-423-10)	5 mL multi-dose vial (ten 0.5 mL doses)	Each 0.5 mL dose contains 24.5 mcg of mercury and each 0.25 mL dose contains 12.25 mcg of mercury (in the form of thimerosal)	Hazardous, D009	2023
Fluad Quadrivalent Over 65 yrs ²	Seqirus	Ten single dose prefilled needleless syringe (NDC 70461-123-04) Carton of 0.5 ml prefilled needleless syringes (NDC 70461-123-03)	0.5 mL single dose prefilled syringes, without needles	No preservatives	Non-hazardous	March, 2023
Flublok Quadrivalent Over 18 yrs ³	Protein Sciences Corp	Ten single dose pre-filled needleless syringe (NDC 49281-723-88) Supplied as carton of 10 (NDC49281-723-10)	0.5 mL single dose prefilled syringes	No preservatives	Non-hazardous	2023
Flulaval Quadrivalent Age ≥ 6 mos ⁴	GlaxoSmithKline	Single dose prefilled syringe (NDC 19515-814-41) Syringe in package of 10: (NDC 19515-814-52)	0.5-mL single-dose prefilled syringes, without needles	No preservatives	Non-hazardous	2023
FluMist Quadrivalent Ages 2-49 yo ⁵	MedImmune LLC	Influenza Vaccine Live, Intranasal Single 0.2 mL (NDC 66019-310-01) Carton of 10 0.2mL prefilled intranasal sprayers: (NDC 66019-310-10)	Single dose prefilled 0.2mL intranasal sprayers	Live attenuated vaccine	Biohazardous	August, 2023

² <https://www.fda.gov/media/135432/download>

³ <https://www.fda.gov/media/123144/download>

⁴ <https://www.fda.gov/media/115785/download>

⁵ <https://www.fda.gov/media/160349/download>

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Fluzone Quadrivalent Age ≥ 6 mos ⁶	Sanofi Pasteur Inc.	Single-dose, prefilled syringe (clear plunger rod), without needle, 0.5 mL (NDC 49281-423-88) Carton of 10 single dose, prefilled syringes 0.5 ml (NDC 49281-423-50)	0.5-mL single-dose prefilled syringes, without needles	No preservatives	Non-hazardous	July 2023
Fluzone Quadrivalent Age ≥ 6 mos	Sanofi Pasteur Inc.	Multi-dose vial, 5 mL (NDC 49281-639-78) Supplied as package of 1 (NDC 49281-639-15)	5-mL multi-dose vial contains 10 doses	Each 0.5 mL dose from the MDV contains 25 mcg mercury and each 0.25 mL dose from the MDV contains 12.5 mcg mercury (in the form of thimerosal)	Hazardous, D009	July 2023
Fluzone High- Dose Quadrialent Over 65 yrs ⁷	Sanofi Pasteur	Single-dose, prefilled syringe, without needle, 0.7 mL (NDC 49281-123-88) Supplied as package of 10 (NDC 49281-123-65).	Suspension for injection in prefilled syringe , 0.7 mL	No preservatives	Non-hazardous	Mar 2023
Fluarix Quadrivalent, Age ≥ 6 mos ⁸	GlaxoSmithKline	Single-dose, prefilled syringe, without needle, 0.5 mL (NDC 58160-909-41) Supplied as package of 10: (NDC 58160-909-52)	0.5 mL single-dose prefilled syringe, without needle	No preservatives	Non-hazardous	2023

⁶ <https://www.vaccineshoppe.com/assets/pdf/vsh/pi/fluqivpi.pdf>

⁷ <https://www.fda.gov/media/139731/download>

⁸ <https://www.fda.gov/media/79278/download>

Flucelvax Quadrivalent, Age <u>> 6 mos</u> ⁹	Seqirus	Ten 0.5 mL single dose pre-filled syringe (NDC 70461-323-04) Package of 10 syringes per carton (NDC 70461-323-03)	0.5 mL single dose pre-filled syringe	No preservative	Non-hazardous	2023
Flucelvax Quadrivalent, Age <u>> 6 mos</u>	Seqirus	5 mL multi-dose vial (NDC 70461-423-11) Individually packaged in a carton (NDC 70461-423-10)	5 mL multi-dose vial	Each 0.5 mL dose from the MDV contains 25 mcg mercury (in the form of thimerosal)	Hazardous, D009	2023

New and updated information in this report includes the following items.

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in Silver Spring, Maryland, on March 7, 2023, to select the influenza viruses for the composition of the influenza vaccine for the 2023-2024 U.S. influenza season. During this meeting, the advisory committee reviewed and evaluated the surveillance data related to epidemiology and antigenic characteristics of recent influenza isolates, serological responses to 2022-2023 vaccines, and the availability of candidate strains and reagents.

Influenza virus strains were selected based on the influenza vaccine production method; egg-based and cell- or recombinant-based.

The committee recommended that the quadrivalent formulation of egg-based influenza vaccines for the U.S. 2023-2024 influenza season contain the following:

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Darwin/9/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021-like virus (B/Victoria lineage); and
- a B/Phuket/3073/2013-like virus (B/Yamagata lineage).

⁹ <https://www.fda.gov/media/115862/download>

The committee recommended that the quadrivalent formulation of cell- or recombinant-based influenza vaccines for the U.S. 2023-2024 influenza season contain the following:

- an A/Wisconsin/567/2022 (H1N1)pdm09-like virus;
- an A/Darwin/6/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021-like virus (B/Victoria lineage); and
- a B/Phuket/3073/2013-like virus (B/Yamagata lineage).

For trivalent influenza vaccines for use in the U.S. for the 2023-2024 influenza season, depending on the manufacturing method of the vaccine, the committee recommended that the A(H1N1)pdm09, A(H3N2) and B/Austria/1359417/2021-like virus (B/Victoria lineage) viruses recommended above for the quadrivalent vaccines be used.

For additional extensive information about the flu vaccine, please visit the CDC website. Relevant links are listed below in the reference section.

Frequently Asked Questions (FAQs) regarding flu vaccine disposal:

What does this guidance provide?

Flu vaccine, including unused or partial vials and syringes, should be disposed of in accordance with applicable federal, state, and local regulations. For the purposes of this webpage, the guidance provided is to address the Resource Conservation & Recovery Act (RCRA) waste categorization requirement as it applies to flu vaccine waste. You should always check all applicable regulations, including your state and local regulations to ensure full compliance and / or please feel free to contact PharmEcology for additional information at info@pharmecology.com or by calling 877-247-7430.

How does the regulation (RCRA) apply to the flu vaccine?

Some of the flu vaccine products contain a preservative called thimerosal which is a mercury-based preservative which has been used for decades in the United States to prevent germ growth in multi-dose vials of vaccines. Under 40 CFR Part 261.24 if the waste contains one or more constituents at concentrations greater than those specified in the maximum concentration of contaminants

for the toxicity characteristic, the waste is considered hazardous. The D009 toxicity characteristic applies for mercury-containing waste when the concentration exceeds the 0.2mg/L threshold (0.2 mg/L = 0.2 mcg/mL). Any flu vaccine containing thimerosal or for which thimerosal was used in the processing will also designate as a hazardous waste, D009.

The flu vaccine that we used is not hazardous. How do I dispose of it?

Flu vaccine waste that does not meet the definition of a hazardous waste under the Resource Conservation and Recovery Act (RCRA) may be disposed of with your other non-hazardous pharmaceutical waste, but you must consider your applicable state or local regulations. In addition, if a flu vaccine product contains live attenuated virus, such as FluMist, it should be disposed of as biohazardous. If you do not have a pharmaceutical waste procedure, please contact us for additional information.

The flu vaccine that we used is hazardous. How do I dispose of it?

If you have determined that your flu vaccine waste meets the definition of a hazardous waste, you must dispose of it as such. This includes appropriately segregating and managing it as a hazardous waste in your facility, usually in a black container. This does not mean placing it in a red sharps container, or another trash container. Please feel free to contact us if you need additional information.

How do we dispose of flu vaccine that is hazardous and also biohazardous?

In the rare instance that it is necessary to dispose of a full or partially used syringe with a needle containing a vaccine with thimerosal, the needle and syringe should be disposed of as dual hazardous and biohazardous waste. An unused vaccine in a vial cannot be both hazardous and biohazardous, as the thimerosal would kill the active virus.

Where may I find more information?

- For additional information on proper disposal of all pharmaceutical waste: please contact us at info@pharmecology.com or by calling 1-877-247-7430.
- For information on the flu, visit the CDC and FDA website using these URL's

1. Summary: 'Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) – United States, 2023-2024'
<https://www.cdc.gov/flu/professionals/acip/summary/summary-recommendations.htm> (article and PDF)
<https://www.cdc.gov/flu/pdf/professionals/acip/acip-2023-24-Summary-Flu-Vaccine-Recommendations.pdf>
2. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023-2024 Influenza Season
https://www.cdc.gov/mmwr/volumes/72/rr/rr7202a1.htm?s_cid=rr7202a1_w
3. FDA Influenza Vaccine for the 2023-2024 Season <https://www.fda.gov/vaccines-blood-biologics/lot-release/influenza-vaccine-2023-2024-season>
4. 2023-2024 CDC Flu Vaccination Recommendation Adopted <https://www.cdc.gov/flu/spotlights/2022-2023/flu-vaccination-recommendations-adopted.htm>