



## PharmEcology<sup>®</sup> Presents Disposal Guidelines for the H1N1 and Seasonal Flu Vaccines (Updated)

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(Wauwatosa, WI - May 19, 2010) PharmEcology Services, WM Healthcare Solutions, Inc.

Recently, several of our clients have asked us to advise them on how to properly dispose of their H1N1 vaccines and their seasonal flu vaccines. In researching flu vaccines, we have seen conflicting recommendations regarding their proper disposal. In response to these requests and to the different recommendations we're seeing, we're providing this summary of the disposal considerations as a service to our clients and to the broader healthcare community.

The U.S. Food and Drug Administration provides a wealth of information about all approved vaccines including the [H1N1 Vaccine](#) and the [Seasonal Flu Vaccine](#). These web sites include links to the actual manufacturer package inserts and other key resources addressing frequently asked questions about the vaccines. These package inserts include specific information about each formulation of the vaccine and we have relied upon that information to develop our recommendations for disposing of the flu vaccines.

Several manufacturers produce 5 mL or 10 mL multidose vials of the vaccines for intramuscular injection. In each case, these formulations contain thimerosal, a mercury derivative, added as a preservative. Each recommended 0.5 mL dose contains approximately 25 mcg mercury. The U.S. EPA defines a waste as hazardous under the toxicity characteristic if the concentration of mercury is equal to or greater than 0.2 mg/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 or a healthcare facility has the test performed and the waste does not fail, any vaccine waste containing thimerosal as a preservative should be managed as a toxic hazardous waste. As a result, all full or partially used multidose vials of the H1N1 flu vaccines and the seasonal flu vaccines should be disposed of as federally hazardous waste.

In addition to producing 5 mL multidose vials of the H1N1 vaccine and the Fluvirin seasonal flu vaccine, Novartis also produces prefilled single-dose 0.5 mL syringes of both vaccines. Although these vaccines are preservative free, thimerosal is used during the manufacturing process. While most of the thimerosal is removed by subsequent purification steps, the final vaccine may contain a trace amount of mercury, less than or equal to 1 mcg per 0.5 mL dose. This amount exceeds the federal threshold noted above and, as a result, these Novartis single-dose formulation should be disposed of as federally hazardous waste.

Novartis also produces a 0.5 ml syringe of the Agriflu seasonal flu vaccine. Because Novartis does not use thimerosal in this manufacturing process, Agriflu can be disposed of as non-hazardous pharmaceutical waste. (Note that PharmEcology recommends that all non-hazardous pharmaceutical waste be incinerated rather than disposed of down the drain or in a landfill).

Sanofi Pasteur, Glaxo Smith Kline, and CSL Limited also produce preservative-free single-dose formulations of the H1N1 vaccine and the seasonal flu vaccines, in 0.25 mL dosages for children under 3 and in 0.5 mL dosages for everyone else. However, all three manufacturers indicate they do not use thimerosal in manufacturing these vaccines and, as a result, these formulations can be disposed of as non-hazardous pharmaceutical waste.

Finally, MedImmune produces a nasal spray H1N1 vaccine and a comparable nasal spray version of the seasonal flu vaccine containing live attenuated versions of viruses. Vaccines containing live attenuated viruses do not contain mercury-based preservatives, so they do not need to be disposed of as federally hazardous pharmaceutical waste. However, as with any vaccine containing an attenuated live virus, any unused vaccine and the sprayer should be disposed of as biohazardous waste.

Generally, prefilled vaccines are supplied in needleless syringes. However, in the rare instances that it is necessary to dispose of a full or partially used sharp syringe containing a vaccine with thimerosal, the sharp should be disposed of as dual hazardous and biohazardous waste.

Also note that in all cases, empty syringes and vials are non-hazardous and can be disposed of in either a red sharps container, for sharps, or in the landfill, for vials.

For a printable summary of this information, including the NDC codes for the specific products, go to [2009 - 2010 H1N1 and Seasonal Flu Vaccines](#).

Additional details about the criteria outlined here are available to subscribers to the PharmE® Waste Wizard and the PharmE® Inventory Analysis.

If you have any additional questions about disposal of the any vaccines or if you have any questions about managing your pharmaceutical waste, please contact us at [info@pharmecology.com](mailto:info@pharmecology.com), call us at 414-292-3959, or visit our web site at [www.pharmecology.com](http://www.pharmecology.com).

ABOUT PHARMECOLOGY, A WASTE MANAGEMENT COMPANY

PharmEcology was founded in 2000 to help healthcare facilities identify and manage pharmaceutical waste. PharmEcology works closely with the healthcare and regulatory communities to insure cost-effective and compliant pharmaceutical waste management programs.

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## 2009 - 2010 H1N1 and Seasonal Flu Vaccines

### H1N1 Flu Vaccine

Manufacturer	Vaccine	Size	NDC	Categorization
CSL Biotherapies	INFLUENZA A (H1N1)	0.5 ML syringe	33332-0519-01	Non-Hazardous
	INFLUENZA A (H1N1)	5 ML vial	33332-0629-10	Hazardous - Mercury Preservative
Medimmune	INFLUENZA A (H1N1) FLUMIST	1 EA syringe	66019-0200-10	Biohazardous
Novartis	INFLUENZA A (H1N1)	0.5 ML syringe	66521-0200-02	Hazardous - Mercury Trace
	INFLUENZA A (H1N1)	5 ML vial	66521-0200-10	Hazardous - Mercury Preservative
	INFLUENZA A (H1N1)	5 ML vial	66521-0200-25	Hazardous - Mercury Preservative
Sanofi Pasteur	INFLUENZA A (H1N1)	5 ML vial	49281-0640-15	Hazardous - Mercury Preservative
	INFLUENZA A (H1N1)	0.5 ML vial	49281-0650-10	Non-Hazardous
	INFLUENZA A (H1N1)	0.25 ML syringe	49281-0650-25	Non-Hazardous
	INFLUENZA A (H1N1)	0.5 ML syringe	49281-0650-50	Non-Hazardous
	INFLUENZA A (H1N1)	0.25 ML syringe	49281-0650-70	Non-Hazardous
	INFLUENZA A (H1N1)	0.5 ML syringe	49281-0650-90	Non-Hazardous

### Seasonal Flu Vaccine

Manufacturer	Vaccine	Size	NDC	Categorization
CSL Biotherapies	AFLURIA	0.5 ML syringe	33332-0009-01	Non-Hazardous
	AFLURIA	0.25 ML syringe	33332-0009-25	Non-Hazardous
	AFLURIA	5 ML vial	33332-0109-10	Hazardous - Mercury Preservative
Glazo Smith Kline	FLUARIX	0.5 ML syringe	58160-0876-46	Non-Hazardous
	FLULAVAL	5 ML vial	19515-0886-07	Hazardous - Mercury Preservative
Medimmune	FLUMIST NASAL VACCINE	1 EA syringe	66019-0107-01	Biohazardous
Novartis	AGRIFLU	0.5 ML syringe	46028-0108-01	Non-Hazardous
	FLUVIRIN	0.5 ML syringe	66521-0112-02	Hazardous - Mercury Trace
	FLUVIRIN	5 ML vial	66521-0112-10	Hazardous - Mercury Preservative
Physicians Total Care	FLUZONE	5 ML vial	54868-6059-00	Hazardous - Mercury Preservative
Sanofi Pasteur	FLUZONE	0.5 ML vial	49281-0009-10	Non-Hazardous
	FLUZONE	0.5 ML syringe	49281-0009-50	Non-Hazardous
	FLUZONE	5 ML vial	49281-0384-15	Hazardous - Mercury Preservative
	FLUZONE HIGH-DOSE	0.5 ML syringe	49281-0385-65	Non-Hazardous
	FLUZONE PEDIATRIC	0.25 ML syringe	49281-0009-25	Non-Hazardous