

Management Guidelines for Medicinals Containing Thimerosal

South Dakota Department of Environment & Natural Resources
Waste Management Program/Hazardous Waste Section

Thimerosal has been used in the process of making certain prescription or non-prescription products, including vaccines and other medicinals, for over 60 years. Containing about 50 percent mercury, thimerosal has been valued as an anti-bacterial agent or as a preservative in vaccine vials that hold a number of doses. Because of the presence of mercury, unusable products containing thimerosal might be regulated as hazardous waste under state and federal waste management requirements. Therefore, South Dakota DENR is providing these guidelines to assist the regulated community within South Dakota to determine options for properly managing waste pharmaceuticals that contain thimerosal.

When products containing mercury become outdated or otherwise deemed unusable, the generator must make decisions regarding their proper management. As with any waste stream, knowledge of the waste constituents help generators choose appropriate disposal options.

To ensure the proper management of wastes, the SDDENR Waste Management Program regulates businesses that generate both solid and hazardous wastes. To determine whether a waste is a hazardous waste, we use Material Safety Data Sheets (MSDS) and other information to assess product constituents (toxicity characteristics) and physical parameters (i.e. flash point, corrosivity, and reactivity characteristics).

State and federal hazardous waste regulations establish that any waste containing 0.2 milligrams per liter (mg/L) or more of mercury, as determined using the EPA-mandated Toxicity Characteristic Leaching Procedure (TCLP), requires management as hazardous waste.

In the case of vaccines manufactured using thimerosal, the amount of thimerosal per dose is included on manufacturer package inserts specific to each product. Testing thimerosal-containing products using the TCLP test provides the specific level of mercury within a specific product. In June 2010, SDDENR contracted a third-party laboratory to analyze the level of mercury in two brands of multi-dose H1N1 vaccines preserved with 0.01 percent thimerosal to obtain general information relative to vaccines containing thimerosal. Based upon calculations (50 ppm mercury/5 mL vial) and test results (40 ppm and 43 ppm/5 mL vial), the department determined the level of mercury in multidose thimerosal-containing vaccines tested exceed the 0.2 ppm TCLP standard for mercury. With the information provided by the manufacturer and results from the TCLP analyses, unused multidose vials containing thimerosal that are destined for disposal need to be managed as a hazardous waste. Consequently, unless a manufacturer or generator has information or a TCLP analysis performed on a vaccine that documents otherwise, unwanted vaccines containing thimerosal should be managed as hazardous waste that exhibits the characteristic of mercury toxicity.

In addition to the multidose vaccines containing thimerosal discussed above, some companies offer a 0.5 mg/L single dose, pre-filled syringe vaccine. Some of these products are labeled "preservative- or thimerosal-free". Preservative-free products may contain trace amounts (less than or equal to 1 microgram/0.5 mL dose) because thimerosal was used during the manufacturing process. The term preservative- or thimerosal-free can be utilized if the manufacturer further purified the product, leaving only trace amounts (less than or equal to 1 microgram/0.5 mL) per dose. Even at this level, calculations indicate mercury would exceed the TCLP standard; therefore these vaccines, if deemed unusable, should be managed as hazardous waste as well.

Some companies verify they did not use thimerosal in the manufacture of the vaccine nor as a preservative in multi-dose vials. As a waste, these unused vaccines can be managed as a non-hazardous pharmaceutical waste. Nasal sprays or other vaccines containing attenuated live H1N1 virus will not contain preservative, so these vaccines can be managed as a non-hazardous biohazardous waste (which may require they be treated and rendered non-infectious before disposal).

Additional Resources

Thimerosal-containing Vaccines

A wealth of information regarding vaccines and the use of preservatives in vaccines is available through various federal and state resources. The following sites currently provide relevant information:

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm>

<http://www.cdc.gov/flu/about/ga/thimerosal.htm>

<http://www.niaid.nih.gov/topics/vaccines/research/pages/vaccines.aspx>

<http://doh.sd.gov/H1N1/default.aspx>

Hazardous Waste Disposal

Healthcare facilities that generate hazardous wastes must calculate the total amount, by weight, of hazardous waste generated on-site within a calendar month. As an overview, the three hazardous waste generator categories are as follows:

Conditionally Exempt Small Quantity Generators (CESQGs): Facilities generating less than 100 kilograms (220 pounds) of toxic hazardous waste and less than 1 kg acute hazardous waste per calendar month.

Small Quantity Generators (SQGs): Facilities generating between 100 and 1000 kg of toxic hazardous waste and less than 1 kg acute hazardous waste per calendar month.

Large Quantity Generators (LQGs): Facilities generating more than 1000 kg toxic hazardous waste or more than 1 kg acute hazardous waste per calendar month.

Options for proper disposal are limited, and determined by the facility's generator category. It is important to note that, for determining the generator category, ALL of a generator's hazardous waste for a calendar month must be included, not just a single waste stream. Therefore, the category determination might include spent mercury-containing lamps, scrap electronics, certain unusable drugs, spent solvents, and other hazardous wastes. Generators should direct questions regarding hazardous waste management to DENR's hazardous waste staff at 605-773-3153 in Pierre, or 605-394-6971 in Rapid City. Additional information is also available on the department's website at:

<http://denr.sd.gov/des/wm/wmp/wmpmainpage.aspx>