Management Guidelines for Vaccines Containing Thimerosal

South Dakota Department of Agriculture & Natural Resources (DANR)
Waste Management Program/Hazardous Waste Section

Thimerosal has been used in the process of making certain prescription or non-prescription products, including vaccines, 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 DANR 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When products containing mercury become outdated or otherwise deemed unusable, the generator must make decisions regarding their proper management.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 SDDANR 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, SDDANR 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:

- Food & Drug Administration (FDA) - *Understanding Thimerosal, Mercury, and Vaccine Safety:* https://www.fda.gov/media/83535/download
- FDA – Thimerosal and Vaccines: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/thimerosal-and-vaccines
- FDA – Thimerosal in Vaccines Questions and Answers: https://www.fda.gov/vaccines-blood-biologics/vaccines/thimerosal-vaccines-questions-and-answers
- Centers for Disease Control and Prevention (CDC) – Thimerosal in Flu Vaccine: https://www.cdc.gov/flu/prevent/thimerosal.htm
- CDC – Thimerosal in Vaccines: https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html
- SD Dept. of Health – Vaccine Information: https://doh.sd.gov/diseases/infectious/flu/default.aspx

Hazardous Waste Disposal

Pharmacies, hospitals, health care and veterinary clinics generate not only infectious medical waste, but pharmaceutical wastes. While infectious medical wastes must be rendered noninfectious prior to disposal as a solid waste, pharmaceutical wastes are different in that some may need to be managed and disposed as a hazardous waste. Healthcare personnel can use the department's guidance to help determine whether a pharmaceutical waste is hazardous waste. It also provides an overview of requirements to ensure hazardous waste pharmaceuticals are properly managed, and offers additional resources to obtain information applicable to your facility.

https://danr.sd.gov/Environment/WasteManagement/HazardousWaste/PharmaceuticalWaste.aspx

Healthcare facilities may direct questions regarding hazardous waste management to DANR'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: https://danr.sd.gov/Environment/WasteManagement/HazardousWaste/default.aspx