Missouri Department of Natural Resources

Is Your Pharmaceutical Waste also Hazardous Waste?

Hazardous Waste Program fact sheet 7/2010

The Missouri Department of Natural Resources' Hazardous Waste Program prepared this fact sheet for Missouri businesses and institutions to help identify and manage pharmaceutical waste considered hazardous waste. This information should not be used in place of state or federal laws.

What is Pharmaceutical Waste?

Pharmaceutical waste can be any of the following discarded or confiscated items:

- Pharmaceutical products.
- Illegal drugs.
- Pharmaceutical precursors or ingredients.

What is Hazardous Waste?

Hazardous waste is any waste that:

- Has been or is intended to be discarded, as described in Code of Federal Regulations 40 CFR 261.2.
- Has not been excluded by federal or state law.
- Is listed (identified) as a hazardous waste in state or federal law.
- Contains materials that shows at least one of the following characteristics:
  - Ignitable.
  - Corrosive.
  - Reactive.
  - Toxic.

Why is it Important to Know if a Pharmaceutical Waste is Hazardous Waste?

Although seemingly harmless in small amounts, pharmaceutical waste can create a serious hazard to human health and the environment if disposed of incorrectly. State and federal laws require wastes identified as hazardous to be handled, stored, treated and disposed of according to the Missouri Hazardous Waste Management law. All non-exempt hazardous waste must be sent to an authorized facility.

How Do I Know Which Pharmaceutical Waste is Hazardous Waste?

There are three main ways pharmaceutical waste can be identified as a hazardous waste:

- It exhibits one or more characteristics of a hazardous waste, as described in 40 CFR 261.24.
- It is specifically identified as a P-listed hazardous waste in 40 CFR 261.33.
- It is specifically identified as a U-listed hazardous waste in 40 CFR 261.33.

Pharmaceuticals that exhibit characteristics of hazardous wastes may contain arsenic, barium, cadmium, chloroform, chromium, lindane, selenium, silver, mercury or m-cresol. Mercury is used as a preservative in some vaccines and in phenylmercuric acetate. M-cresol is used as a preservative in some insulin and vaccines. In addition, pharmaceuticals that are ignitable, such as solutions containing more than 24 percent alcohol, or are highly corrosive such as compounding chemicals, can be hazardous waste.

If you are unsure if a pharmaceutical waste is a hazardous waste, contact the manufacturer. The manufacturer will be able to tell you the active ingredients in the pharmaceutical. The manufacturer should also be able to provide a Material Safety Data Sheet, which explains the potential hazards of the chemicals used in a product. It may also be necessary to analyze the pharmaceutical waste to determine if it is hazardous. More guidance about determining if waste is hazardous or not is available in the department's fact sheet ***Does Your Business Generate Hazardous Waste?*** (PUB0117), available on the department's website at www.dnr.mo.gov/pubs/pub117.pdf.

P-listed hazardous wastes include acutely hazardous commercial chemical products that have been or intend to be discarded. P-listed hazardous wastes have extremely hazardous properties that make them harmful in very small quantities. U-listed hazardous wastes include commercial chemical products that have been or intend to be discarded.

In order to qualify as a U- or P-listed hazardous waste, the waste must meet these two criteria:

1. The waste must be a commercial chemical product. Commercial chemical products are unused chemicals, manufacturing intermediates of a chemical, off-specification variations of a chemical, residues in containers that are not "Resource Conservation and Recovery Act, or RCRA, empty" or cleanup residue or debris of any chemical named on the U or P list. More discussion about RCRA empty is available below.
2. The commercial chemical product's sole active ingredient must be specifically listed on the U or P list. Sole active ingredient is interpreted as the ingredient that performs the main function of the product. Fillers, colorants, carriers or the like are not considered active ingredients. The commercial chemical product is not a U- or P-listed hazardous waste if it has two or more active ingredients, even if all the ingredients are listed on the U or P list.

The active chemical ingredients listed in paragraphs (e) and (f) of 40 CFR 261.33 are listed by chemical name, not necessarily by their common or commercial name. Most chemicals can be identified by more than one name. Cross-referencing chemical synonyms and verifying by Chemical Abstract Number must be done to confirm the chemical does not have another name on the P or U list. See the U.S. Environmental Protection Agency's publication, ***Consolidated List of Chemicals Subject to EPCRA and Section 112(r) of the Clean Air Act, EPA550-B-01-003*** available online at www.epa.gov/swercepp/pubs/title3.pdf.

A list of common pharmaceutical precursors and ingredients that are U- or P-listed hazardous wastes is given in the following tables:

Acute Hazardous Waste	Substance
P001	Warfarin >0.3%
P012	Arsenic trioxide
P042	Epinephrine (not epinephrine salts)
P046	Phentermine
P075	Nicotine
P188	Physostigmine salicylate
P204	Physostigmine

Note: Medicinal nitroglycerin is not considered a P081 listed hazardous waste because it is not reactive.

Hazardous Waste	Substance
U010	Mitomycin C
U034	Chloral Hydrate
U035	Chlorambucil
U044	Chloroform
U058	Cyclophosphamide
U059	Daunomycin
U075	Dichlorodifluromethane
U058	Cyclophosphamide
U059	Daunomycin
U075	Dichlorodifluromethane
U089	Diethylstilbestrol
U117	Ethyl Ether
U121	Trichloromonofluromethane
U122	Formaldehyde
U129	Lindane (also can fail for toxicity)
U132	Hexachlorophene
U141	Isosafrole
U150	Melphalan
U182	Paraldehyde
U187	Phenacetin
U188	Phenol
U200	Reserpine
U201	Resorcinol
U202	Saccharin
U203	Safrole
U205	Selenium Sulfide
U206	Streptozotocin
U220	Toluene

When Is the Container that Held the Pharmaceutical Hazardous Waste Considered "RCRA Empty" and Not a Hazardous Waste?

According to 40 CFR 261.7(b)(3), a container or inner liner removed from a container that held an acute hazardous waste is empty if one of the three following procedures is followed:

- The container is triple rinsed with a solvent capable of removing the acute hazardous waste. The rinsate resulting from this process is considered an acute hazardous waste. The solvent may also exhibit a hazardous waste characteristic, such as ignitability.
- The container has been cleaned by another method that has been shown in scientific literature, or by tests conducted by the generator, to achieve equivalent removal. If you decide to use an alternative cleaning method, you must document the equivalency of the method. It is a good idea to discuss the use of an equivalent removal method with the Missouri Department of Natural Resources' Hazardous Waste Program at 573-751-3176.
- The inner liner that prevented contact between the acute hazardous waste and the container is removed.

According to 40 CFR 261.7(b)(1), a container or inner liner removed from a container that held a non-acute hazardous waste is empty if all wastes have been removed that can be removed using "commonly employed practices" for that type of container and one of the three following criteria are met:

- No more than 2.5 centimeters (1 inch) of residue remains on the bottom of the container or liner.
- No more than 3 percent by weight of the total capacity of the container remains if the container is less than or equal to 119 gallons in size.
- No more than 0.3 percent by weight of the total capacity of the container remains if the container is more than 119 gallons in size.

Commonly employed practices of removing wastes from a container include pouring, pumping and aspirating. The method chosen must be appropriate for the type of container you are emptying. For example, if turning a vial upside-down and pouring out the pharmaceutical hazardous waste removes more of the waste than aspirating, or sucking out the waste, then the pharmaceutical hazardous waste should be poured out. The RCRA empty container can now be discarded as a regular solid waste so long as the container itself is not hazardous waste. Packaging that once contained pharmaceutical hazardous waste, such as those surrounding pills, gum or patches, may be discarded as regular solid waste unless visibly soiled or overtly contaminated with the pharmaceutical hazardous waste.

What About Pressurized Containers, such as Aerosol Inhalers?

Empty aerosol inhalers can be either disposed as a solid waste or recycled. If the aerosol inhaler still contains a pharmaceutical or propellant, you must make a hazardous waste determination for the inhaler. Most propellants in aerosol inhalers are ignitable, making the inhaler a characteristic hazardous waste if it is still pressurized.

What about Intravenous, or IV, Pharmaceuticals?

A hazardous waste determination must be made on the intravenous pharmaceuticals; however, the type of determination depends on the circumstances. Intravenous pharmaceuticals may not be completely given to a patient, due to allergic reaction or change in pharmaceutical choice while dosing. The part of the IV infusion not given to the patient qualifies as a commercial chemical product since it was not used for its intended purpose. A determination for both listed and characteristic hazardous waste must be made for the remaining IV pharmaceuticals.

Intravenous pharmaceuticals completely administered to the patient according to normal IV practices do not qualify as a commercial chemical product since it was used for its intended purpose. The IV pharmaceutical would not qualify as a listed hazardous waste; however, you still need to determine if it is a characteristic hazardous waste.

If you determine the IV pharmaceuticals are a pharmaceutical hazardous waste, the IV bag and tubing that contained the pharmaceutical hazardous waste must meet the RCRA empty criteria or be disposed of as hazardous waste.

What If My Business Produces One of These Wastes?

Your business or institution may be considered a hazardous waste generator if you produce any of the hazardous wastes listed in the previous tables. If you produce or accumulate more than 1 kilogram or 2.2 pounds of a P-listed waste per month or at any one time, your business is considered a large quantity hazardous waste generator. Please refer to the appropriate state and federal laws and regulations and request the fact sheet, ***Does Your Business Generate Hazardous Waste?*** (PUB117) from the department's Hazardous Waste Program, available online at www.dnr.mo.gov/pubs/pub117.pdf.

Where Can I Find a Copy of the State and Federal Hazardous Waste Laws and Regulations?

- Missouri Revised Statutes, or RSMo, including the Missouri Hazardous Waste Management Law, are available from the Revisor of Statutes, 573-526-1288, or online through the Missouri General Assembly website at www.moga.state.mo.us.
- Missouri Code of State Regulations, or CSR, is available from the Missouri Secretary of State's Office, 573-751-4015, or online at www.sos.mo.gov/adrules/csr/csr.asp.
- The Code of Federal Regulations is available online at www.gpoaccess.gov/cfr/. Copies may be purchased from a U.S. Government Bookstore, the U.S. Government Printing Office or from a commercial information service such as the Bureau of National Affairs.

For More Information

Missouri Department of Natural Resources
Hazardous Waste Program
Permits Section
P.O. Box 176
Jefferson City, MO 65102-0176
800-361-4827 or 573-751-3553
www.dnr.mo.gov/env/hwp/permits.htm