

Epinephrine Fact Sheet:

This fact sheet provides information to assist healthcare facilities with hazardous waste determinations regarding epinephrine wastes

Healthcare facilities that dispose of wastes containing **epinephrine salts** do not fall under the same PO42 hazardous waste classification as **epinephrine in the free base form**.

Since there are formulations of epinephrine that must still be managed as hazardous wastes. Healthcare facilities are advised to make sure they are classifying their wastes correctly before changing disposal practices. This fact sheet provides some relevant information to assist with that determination.

Background

Certain pharmaceutical wastes are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA). (For a more complete explanation of RCRA hazardous waste rules go to <http://www.hercenter.org/hazmat/hazardouswaste.cfm>. RCRA typically applies to chemicals that have been used and discarded. The rules can also cover unused chemicals that are being discarded for various reasons. For example, they may be off-specification or expired, they may have been spilled and cleaned up, or they may be residues left in containers. **Note that an inspector could view an expired drug product as waste, even though the facility has not yet made the decision to discard that expired drug product.** Most facilities use reverse distribution to maximize credits for expired products. EPA and various states have begun limiting the reverse distribution of expired products that are disposed of as hazardous waste and are not creditable. Check with your state to ensure proper management of these items.

The RCRA rules include four lists that identify certain wastes as hazardous, including two lists of specific chemicals that are subject to regulation (the P- and U-lists, found in 40 CFR 261.33). The P- and U-lists differ in their degree of risk: U-listed wastes are “toxic”, while P-listed wastes are “acutely toxic”, meaning that they can cause death or irreversible illness at low doses. Therefore, their regulatory requirements for P-listed wastes are more stringent than the requirements for U-listed wastes. There are also some chemicals listed on the P- and U-lists that are inherently ignitable, corrosive, or reactive. Nitroglycerin is an example of a reactive P-listed chemical. The P- and U-lists include commercial chemical products, which may be found in healthcare facilities.

In addition, it is important to note that the regulatory clarification presented in this fact sheet applies to the federal hazardous waste regulations. **Some states may regulate epinephrine salts more stringently than the federal regulations require, and may even decide to continue regulating the salts as RCRA hazardous wastes.** Therefore, we recommend that the regulated community contact their state regulatory agency to ascertain the scope of the PO42 listing in their state. To find a hazardous waste point of contact in your state, see <http://www.hercenter.org/hz.cfm>.

EPA Clarification

Epinephrine is one of the commercial chemical products found on the P-list (its specific designation is PO42). EPA has received a number of inquiries from their regional offices, state agencies and healthcare facilities regarding whether the RCRA listing PO42 includes epinephrine salts. On October 15, 2007, the EPA pushlisted a memorandum that addressed the scope of the hazardous waste listing of epinephrine. The memorandum clearly states the epinephrine salts are not included within the scope of the PO42 listing. For the full text of the memorandum, see www.epa.gov/region1/healthcare/pdfs/Epimeno_Final.pdf.

There are many common drug formulations that contain epinephrine in some form, including those used to treat cardiac arrest and allergic reactions. Due to the insolubility of epinephrine base, all finished dosage form of epinephrine used in healthcare (solutions, aerosols, etc.) are either hydrochloride, bitartrate, or borate salts. EPA distinguishes epinephrine salts from the base chemical epinephrine (CAS #51-43-4).

Applications of EPA's Clarification

Although EPA's memorandum is helpful, hospitals and other facilities responsible for disposing of pharmaceutical wastes must still determine whether the ruling applies to each form of epinephrine that appears in their particular drugs and resultant wastes. Specifically, applicable drugs must be evaluated to determine whether their ingredients fall under the definition of epinephrine as it appears on the P-list, or under the classification of epinephrine salts covered in the memorandum.