

## Epinephrine Fact Sheet:

This fact sheet provides information to assist healthcare facilities with hazardous waste determinations regarding epinephrine wastes (P042).



Healthcare facilities that dispose of wastes containing **epinephrine** should be aware of a memorandum recently published by EPA. The memorandum makes it clear that **epinephrine salts** do not fall under the same P042 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, the 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 P042 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 P042). EPA has received a number of inquiries from their regional offices, state agencies and healthcare facilities regarding whether the RCRA listing P042 includes epinephrine salts. On October 15, 2007, the EPA published a memorandum that addressed the scope of the hazardous waste listing of epinephrine. This memorandum clearly states that epinephrine salts are not included within the scope of the P042 listing. For the full text of the memorandum, see [www.epa.gov/region1/healthcare/pdfs/EpiMemo\\_Final.pdf](http://www.epa.gov/region1/healthcare/pdfs/EpiMemo_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 forms 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).

## **Application 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.

To further assist healthcare facilities with their product determinations, the Healthcare Environmental Resource Center (HERC) contracted PharmEcology Associates, LLC to review this fact sheet and provide additional guidance. Based on information provided by PharmEcology Associates, LLC, all finished dosage forms of epinephrine are in the form of the salt. However, some forms may exhibit the characteristic of ignitability, and they must be managed as D001 ignitable hazardous waste. Not being a P-listed waste, however, may have a great impact on hazardous waste generator status. Bulk epinephrine powder or

crystals will often be the base, and would still need to be managed as P042 if discarded.

If you wish to do your own evaluations, HERC has compiled the following information. Please note that this does not necessarily represent EPA's interpretation, but HERC staff believes that it is consistent with the chemical facts of the matter, and should serve as a reliable guide.

### **The "Water Solution" Test**

Epinephrine salts are formed when you dissolve pure "epinephrine base" in acid. Epinephrine base is only sparingly soluble in water, while the salts dissolve readily. When used in drug applications, epinephrine is usually administered in the salt form, as a dilute water solution. Therefore, as a rough rule of thumb, if the product is in a water solution, it's the salt. If the product is not in a water solution, there's a chance it's the base, so further evaluation is necessary.

### **Available Tools**

A useful source of information when evaluating chemicals is the [Merck Index](#), an encyclopedia of chemicals, drugs and biologicals with over 10,000 monographs on single substances or groups of related compounds. It is published by the United States pharmaceutical company [Merck & Co](#). The Merck Index is also available by subscription in an electronic searchable form, commonly carried by research libraries, as well as in a web-accessible form.

### **Additional Rules to Consider**

While epinephrine salts are not listed wastes when discarded, a chemical or formulation containing an epinephrine salt can still be a characteristic RCRA hazardous waste (under a different Subpart of the RCRA regulations), if it exhibits a characteristic of hazardous waste (*i.e.*, ignitable, corrosive, reactive, or toxic) when discarded. In particular, inhalers may exhibit the ignitability characteristic based on their alcohol content. Since only 40 chemicals are listed in the toxicity characteristic, and epinephrine is not one of them, it is never a hazardous waste under the toxicity characteristic. Also, no instances of epinephrine meeting the definition of a corrosive or reactive waste have been identified. For more information on waste determinations and characteristic wastes, see <http://www.hercenter.org/hazmat/hazdeterm.cfm#characteristic>.

Prepared by Healthcare Environmental Resource Center ([www.hercenter.org](http://www.hercenter.org)).  
For information on HERC, please contact:  
[Paul Chalmer](#), NCMS (734) 995-4911