

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 1
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BOSTON, MA 02114-2023

December 30, 2008

Thomas J. Shandera, RN, MPH, CIC
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Bangor, ME 04401

Dear Mr. Shandera:

This letter addresses questions you raise in your email inquiry to Lisa Papetti dated May 29, 2008 which was referred to my staff for response. I apologize for the delay in responding. We have been researching your request to provide you as complete and accurate response as possible. We have identified each of the questions in your original email followed by the corresponding answer.

In order for materials to be hazardous wastes under the RCRA program, and therefore be subject to RCRA regulations, they must first be classified as solid waste. Materials become solid waste when they are discarded or are intended for discard (40 CFR 261.2). Since all of the items for which you request a determination are disposed of or are intended for discard, they are solid waste. They become hazardous wastes if they are "listed" in 40 CFR Part 261, Subpart D, or exhibit one or more of the hazardous waste characteristics; i.e., ignitability, corrosivity, reactivity, or toxicity (40 CFR 261.20-261.24).

We are providing general guidance about whether particular waste streams are within what EPA has classified as "listed" hazardous waste. In contrast, it generally is not possible to specify in general guidance whether or not all wastes within a waste stream are characteristic hazardous wastes, since the particular characteristics of wastes within a waste stream may vary. It ultimately is the responsibility of each generator to determine whether a particular waste is either a listed or characteristic hazardous waste. The basis for each determination should be documented and retained in the generator's files.

Under RCRA, States may regulate hazardous wastes more stringently or more broadly in scope than the EPA. Since the Maine Department of Environmental Protection (MEDEP) has been authorized to implement the hazardous waste program in lieu of the federal program and may regulate certain wastes more stringently than the federal regulations, we recommend that you consult with the MEDEP for their interpretation of their regulations.

The EPA's Office of Solid Waste is evaluating national guidance regarding the status of various pharmaceutical wastes generated in a healthcare setting. If and when such guidance is issued, it is possible that it may take a different interpretation on a particular issue than is taken in this letter. Any such national guidance could supersede the guidance set forth in this letter. However, this letter expresses the Region's current interpretations which will continue to apply unless and until they are changed. Also, please note the Agency has recently published a proposed rule regarding the proposed inclusion of hazardous pharmaceutical wastes under the Universal Waste Rule (UWR) (see the following link):

<http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm> .

This letter addresses your questions regarding the status of various products which have been used and then are being discarded. The rules could be different for products that never have been used but are being discarded (for example, disposal of unused products that contain a P-listed material as the sole active ingredient would be regulated as a listed waste). Thus, this guidance should not be relied upon in the event you are discarding unused materials.

1. Does nicotine gum that has been chewed constitute hazardous waste?

Nicotine gum that has been chewed is not a listed waste. Nicotine gum is considered a P-listed (P075) commercial chemical product (CCP) formulation of nicotine as the sole active ingredient. However, once the gum has been chewed (and the nicotine administered), the product would be considered used for its intended purpose. It is no longer considered a CCP and, therefore, not a P-listed hazardous waste when disposed (see EPA guidance link below). However, the waste's properties then should be evaluated to determine if it exhibits a hazardous waste characteristic (i.e., ignitability, corrosivity, reactivity or toxicity). To assist in making this determination for a particular formulation of nicotine gum, we recommend that you consult with the supplier or manufacturer of the product to ensure the used product would not exhibit any of the hazardous waste characteristics.

CCPs used for their intended purpose, RCRA Online #11459, 4/21/89:

[http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/BCFA96341ABF27668525670F006BDFD2/\\$file/11459.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/BCFA96341ABF27668525670F006BDFD2/$file/11459.pdf)

2. Do nicotine patches that have been worn constitute hazardous waste?

Nicotine patches that have been worn are not a listed hazardous waste. Like nicotine gum, nicotine patches are also considered a P-listed (P075) commercial chemical product (CCP) formulation of nicotine as the sole active ingredient. However, once the patch is removed, the product is considered to have been used for its intended purpose. It is no longer a CCP and, therefore, not a P-listed hazardous waste when disposed. The waste's properties should be evaluated to determine if it exhibits a hazardous waste characteristic

(i.e., ignitability, corrosivity, reactivity or toxicity). We suggest you consult with your supplier or manufacturer to make sure that the used nicotine patches will not be characteristic before disposing of them as a non-hazardous waste.

3. Do Epi-pens that have been used constitute hazardous waste?

Based upon EPA guidance documents (links below), used Epi-pens are not a P-listed hazardous waste. It is our understanding that most of the chemical that is used in medical applications is one of several epinephrine salts, and epinephrine salts are not included in the scope of the commercial chemical product listing of epinephrine base (listed as P042) at 40 CFR 261.33. However, note some manufacturers' MSDS information identifies the product as that of adrenalin base. Therefore, we recommend checking with the supplier or manufacturer to verify the proper classification of the active ingredient of the Epi-pen product as either epinephrine base or epinephrine salt (which impacts disposal requirements for unused Epi-pens). Epi-pens are syringe-like, and according to EPA guidance, any remaining residues in such a dispensing instrument are considered to have been used for their intended purpose and therefore would not be considered a P-listed hazardous waste. The syringe-like instruments are not considered to be "containers," thus the rules classifying as hazardous wastes non-empty containers that have held hazardous wastes do not apply. The used Epi-pen and remaining formulation should be evaluated to determine if it exhibits a characteristic of hazardous waste (i.e., ignitability, corrosivity, reactivity or toxicity). We recommend you check with your supplier or manufacturer for information related to the possible hazardous characteristics of this type of waste.

See RCRA Online #14778, 10/15/07 letter regarding scope of epinephrine (P042) listing:
[http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2F701627EB73B2AB852573D2005E0B4F/\\$file/14778.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2F701627EB73B2AB852573D2005E0B4F/$file/14778.pdf)

Also, see RCRA Online #14788, 4/14/08 letter referencing prior determinations of residual epinephrine in a syringe and the scope of P042 listing:
[http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/\\$file/14788.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/$file/14788.pdf)

4. Do glass ampules from which epinephrine has been withdrawn constitute hazardous waste?

We are providing answers to both the salt and the base forms of epinephrine. As noted above, epinephrine salt when discarded (per EPA guidance above) is not included in the P list of hazardous wastes, and therefore is not considered a hazardous waste. If the discarded ampule contains an epinephrine salt, it is not a "listed" waste. The formulation may, however, be considered a RCRA hazardous waste if it exhibits a characteristic of hazardous waste (i.e., ignitability, corrosivity, reactivity or toxicity). We recommend you check with your supplier or manufacturer for information related to the possible hazardous characteristics of this type of waste.

When epinephrine is the base form and the sole active ingredient of a formulation, the remaining waste in the ampule would constitute an unused commercial chemical product, a P042 acutely hazardous waste when disposed. Unlike an Epi-pen or a syringe, an ampule is considered to be a "container."

Whenever the waste is characteristic hazardous or listed hazardous, the ampule would be subject to applicable hazardous waste requirements unless the generator is able to comply with the "RCRA empty" requirements which pertain to removal of residues of hazardous waste in containers (40 CFR 261.7). However, due to the size of the ampule, it may not be practical to attempt to remove residues. Thus, alternatively, if hazardous, the Agency would recommend you consider disposal of the entire container (ampule and residue) as a hazardous waste.

5. Do glass bottles containing nitroglycerin, some or all of which has been administered to a patient, constitute hazardous waste?

We believe the State of Maine regulates medical nitroglycerine as a listed acutely hazardous waste (P081) when disposed. We recommend that you check with the State for their latest interpretation of their regulations. The State is more stringent than the EPA in the regulation of nitroglycerin as follows. In the early days of RCRA, EPA regulated the unused commercial chemical product nitroglycerine, which was listed solely for reactivity, as a listed acutely hazardous waste (P081) when disposed. On February 1, 2002, EPA revised its program and the new mixture and derived-from rules went into effect. These provide that for a waste that has been listed solely for the characteristic of ignitability, corrosivity or reactivity, the waste is no longer regulated if it does not exhibit any hazardous waste characteristic. P081 is listed solely for reactivity, and because EPA presumes that medical nitroglycerine is not reactive, it would not be regulated as hazardous waste under EPA's new rule. However, under the RCRA statute and regulations, a state would have to adopt this new, less stringent provision in order for it to be in effect in that particular state. Until a state adopts this provision or in cases where they decide not to, the previous more stringent requirement remains in effect. Thus, in the State of Maine, because Maine has not adopted nor been authorized for the new mixture and derived-from rule, the earlier, more stringent rules continue to be in place and medicinal nitroglycerine remains regulated as a P081 listed hazardous waste.

The glass bottles which have held the nitroglycerine are considered to be containers. As discussed in item 4 above, the container would be subject to hazardous waste requirements unless the generator is able to comply with the "RCRA empty" requirements which pertain to the removal of residues of hazardous waste in containers (40 CFR 261.7). Any waste removed from the container would have to be managed in compliance with applicable hazardous waste requirements. If the waste is not removed, then the bottle and the residue within it would have to be managed as a hazardous waste.

Below is a link to a previous RCRA Online document (#14654) which relates to this question.

<http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f77acfec572de8897f85256d1600748bcb!OpenDocument>

If you have any questions on this information, please contact Robin Biscaia in our Hazardous Waste Unit at (617) 918-1642. You may also wish to contact Mike Hudson, Supervisor of the Hazardous Waste Enforcement Unit of the Maine Department of Environmental Protection at (207) 287-7994, or email at michael.s.hudson@maine.gov since they are authorized to manage the hazardous waste program in the State of Maine.

Sincerely,



Mary Sanderson, Chief
Remediation and Restoration II Branch
Office of Site Remediation and Restoration

cc: Michael Hudson, Maine DEP
Stuart Gray, Chief, Hazardous Waste Unit
Deborah Brown, Chief, RCRA Enforcement Unit
Jeff Fowley, RCRA Attorney