



Minnesota
Pollution
Control
Agency

Alternate Method to Evaluate Pharmaceutical Waste for the Lethality Characteristic

Waste/Hazardous Waste 4.45b • August 2010

Pharmaceutical waste

Pharmaceutical waste includes expired drugs, patients' personal medications, waste materials containing excess drug (syringes, IV bags, tubing, vials, etc.) and drugs that are intended to be discarded. You must evaluate each of these wastes to determine whether it is hazardous and dispose of it accordingly.

This fact sheet offers guidance only on evaluating pharmaceutical waste for the lethality characteristic. You must also determine whether each pharmaceutical waste is hazardous due to a characteristic other than lethality or to its status as a listed hazardous waste.

For more information about evaluating pharmaceutical waste, see Minnesota Pollution Control Agency (MPCA) hazardous waste fact sheet #4.45a, [Evaluating Pharmaceutical Wastes](http://www.pca.state.mn.us/publications/w-hw4-45a.pdf) at: www.pca.state.mn.us/publications/w-hw4-45a.pdf.

The lethality characteristic

"Lethality" is a hazardous waste characteristic specific to Minnesota. A waste is considered "lethal" if the median

lethal dose of a representative sample of the waste is below specified limits. For more information about the lethality characteristic, see MPCA hazardous waste fact sheet #2.05, [The Lethality Characteristic](http://www.pca.state.mn.us/publications/w-hw2-05.pdf) at: www.pca.state.mn.us/publications/w-hw2-05.pdf.

Under the Minnesota Hazardous Waste Rules, if a generator of a pharmaceutical waste does not have median lethal dose data for that waste, the waste is presumed to be lethal and must be managed as a hazardous waste. Because the median lethal dose data needed to evaluate whether a pharmaceutical waste is a lethal hazardous waste is not always readily available, the MPCA approved an alternative to the Rule requirement in 2005, and reapproved a revised version of this alternate method in 2010.

Generators must receive approval from the MPCA to apply the alternate method.

The alternate method

The revised alternate method for evaluating pharmaceutical waste for the lethality characteristic (alternate method) assumes a pharmaceutical waste is lethal if it is contained in or described by any of the following six risk criteria groups:

1. Carcinogen
2. Chemotherapy agent
3. Combination U/P-List drug
4. Endocrine disruptor
5. NIOSH hazardous drug
6. OSHA hazardous drug

If a pharmaceutical waste is not contained in or described by any of the risk criteria groups, generators may assume it is not lethal regardless of its median lethal dose.

Waste evaluated under the alternate method as non-lethal may not be assumed to be non-hazardous. The waste still must be evaluated for all other hazardous waste characteristics and for listing.

To access hazardous waste publications on MPCA's Web site:

- Click on **Waste** in the menu bar
- Click on **Publications** in the drop-down menu bar
- Click on **Hazardous Waste Publications** in the bulleted list or
- For health-care related documents, click on **Health Services** in the **SEE ALSO** box in the upper right

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Risk criteria group definitions

Carcinogen

A drug listed that is known or is reasonably anticipated to be a human carcinogen in the most recent published Report on Carcinogens (Report), published by the U.S. National Toxicology Program (NTP) biennially, every even year. The most recent report is available on the NTP Web site <http://ntp.niehs.nih.gov>.

Chemotherapy agent

A drug approved by the U.S. Food and Drug Administration (FDA) for treatment of cancer or used by a healthcare facility for off-label treatment of cancer; it acts by causing cell death or by significantly decreasing cell growth or reproduction.

Combination U/P-listed drug

A drug with more than one active ingredient containing at least one active ingredient on the P-List or the U-List, as defined in [Minn. R. 7045.0135](#). Drugs used for their intended purpose are not subject to this definition. The P-List and U-List are available in MPCA hazardous waste fact sheets #2.02, [P List of Acute Hazardous Wastes](#), and #2.03, [U List of Hazardous Wastes](#), at: www.pca.state.mn.us/waste/pubs/business.html.

Endocrine disruptor

A drug that meets the definition of an endocrine disrupting compound (EDC) in the January 15, 2008, MPCA report to the Minnesota Legislature titled [Endocrine Disrupting Compounds](#). The report is available on the MPCA Web site at: www.pca.state.mn.us/publications/reports/lrp-ei-1sy08.pdf.

The MPCA considers that at least the drugs identified in Table 1, as amended, meet this definition for the purposes of the alternate method.

Note: Epinephrine of 0.24% or less concentration is not considered a lethal hazardous waste under the alternate method. For a detailed discussion of the regulated status of epinephrine wastes, see MPCA hazardous waste fact sheet #3.35, [Regulatory Consensus on Health Care Issues](#), at: www.pca.state.mn.us/publications/w-hw3-35.pdf.

NIOSH hazardous drug

A drug listed or that meets one or more of the hazardous drug criteria in Appendix A of the U.S. National Institute for Occupational Safety and Health (NIOSH) Publication #2004-165, NIOSH Alert: [Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Setting](#). This publication is available on the NIOSH Web site www.cdc.gov/niosh.

OSHA hazardous drug

A drug listed in Appendix VI:2-1 or that meets one or more of the hazardous drug criteria contained in Section VI, Chapter 2, Subsection II of the U.S. Occupational Safety & Health Administration (OSHA) Directive [TED 01-00-015](#), OSHA Technical Manual, OSHA, as amended. This directive is available on the OSHA Web site www.osha.gov.

When can I use the alternate method?

You may use the alternate method only to evaluate pharmaceutical waste for the lethality characteristic. To use the alternate method, the generator must submit a petition to the MPCA. Petition templates are available from MPCA hazardous waste staff.

You must also evaluate pharmaceutical waste to determine whether it:

- displays any hazardous waste characteristics other than lethality
- is listed

Table 1: Drugs considered as EDCs for purposes of the alternate method

All human and animal hormone pharmaceutical wastes, including but not limited to:

- All Amino Acid-derived Hormones and their synthetic analogues; for example Dopamine, Serotonin, and Thyroxine.
- All Protein or Peptide Hormones and their synthetic analogues; for example Insulin, Oxytocin, and Glucagon.
- All Steroid Hormones and their synthetic analogues; for example Cortisol, Progesterone, and Vitamin D.
- All Fatty Acid-derived Hormones and their synthetic analogues; for example Prostaglandins, Thromboxane, and Leukotrienes.

*Note: Specific hormones identified here are only examples. All hormone pharmaceuticals of these hormone types are included, not just the specific examples listed here.

For guidance evaluating and disposing of pharmaceutical waste, see MPCA hazardous waste fact sheet #4.45a, [Evaluating Pharmaceutical Wastes](#), available from the [Hazardous Waste Publication](#) and [Health Care](#) pages.

The alternate method applies only to pharmaceutical waste; do not use it to evaluate non-pharmaceutical waste. To evaluate non-pharmaceutical waste for lethality, see MPCA hazardous waste fact sheet #2.05, [The Lethality Characteristic](#), available from the MPCA [Hazardous Waste Publication](#) page.

How do I show a pharmaceutical waste is non-lethal?

If applying the alternate method, you must maintain documentation showing that a pharmaceutical waste is not contained in any of the risk criteria groups.

Instead of the alternate method, any generator may also evaluate any pharmaceutical waste under the median lethal dose standards contained in the Minnesota Hazardous Waste Rules. A pharmaceutical waste with a calculated median lethal dose greater than the thresholds contained in the Rules may be considered non-lethal, regardless of whether it would otherwise be considered lethal under the alternate method. If calculating the median lethal dose of a waste pharmaceutical, you must ensure you evaluate it for all reasonable exposure routes. For detailed directions on calculating the median lethal dose, see the 'Calculating the estimated LD₅₀ of a waste' section of MPCA hazardous waste fact sheet #2.05, [The Lethality Characteristic](#).

If you do not maintain documentation showing either that a pharmaceutical waste is not contained in any of the risk criteria groups or that its calculated median lethal dose is greater than the Rule thresholds, you must assume that pharmaceutical waste is lethal and manage it as a hazardous waste.

More Information

Your metropolitan county and the MPCA hazardous waste staff can answer questions about the waste evaluation process. Contact your metro county office or your nearest MPCA regional hazardous waste office.

The Minnesota Technical Assistance Program staff can provide information about waste reduction practices.

Metro County Hazardous Waste Offices

Anoka	763-422-7093
Carver	952-361-1800
Dakota	952-891-7557
Hennepin	612-348-3777
Ramsey	651-266-1199
Scott	952-496-8475
Washington	651-430-6655
Web sites	www.co.[county].mn.us

Minnesota Pollution Control Agency

Toll free (all offices)	1-800-657-3864
Brainerd	218-828-2492
Detroit Lakes	218-847-1519
Duluth	218-723-4660
Mankato	507-389-5977
Marshall	507-537-7146
Rochester	507-285-7343
St. Paul	651-296-6300
Willmar	320-214-3786
Web site	www.pca.state.mn.us

Minnesota Technical Assistance Program

Toll-free	1-800-247-0015
Minneapolis	612-624-1300
Web site	www.mntap.umn.edu

U.S. National Institute for Occupational Safety and Health (NIOSH)

Web site	www.cdc.gov/niosh
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U.S. OSHA

Web site	www.osha.gov
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