Alternate Method to Evaluate Pharmaceutical Waste for the Lethality Characteristic

Pharmaceutical waste includes expired drugs, waste materials containing excess drug (syringes, IV bags, tubing, vials, etc.), and any other drugs or medications that cannot be used or are intended to be discarded. Assume all pharmaceutical waste is hazardous waste and manage it accordingly, unless you evaluate each drug or medication and can document that it is non-hazardous.

This fact sheet offers guidance only on evaluating pharmaceutical waste for the lethality characteristic. To document that a pharmaceutical waste is non-hazardous, you must also show that it is not a listed hazardous waste and that it does not exhibit any of the other hazardous waste characteristics (ignitability, oxidizer, reactivity, corrosivity, and toxicity).

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

Lethality characteristic

Lethality is a hazardous waste characteristic specific to Minnesota. A waste is lethal if the median lethal dose (LD_{50}) of the waste is below certain limits. For more information about the lethality characteristic, see MPCA fact sheet #w-hw2-05, The Lethality Characteristic at: http://www.pca.state.mn.us/publications/w-hw2-05.pdf.

Because LD_{50} data is sometimes not available, the MPCA has approved an alternative method to evaluate pharmaceutical wastes for the lethality characteristic. Though generators previously had to individually petition the MPCA to use this alternate method, the MPCA will now allow any pharmaceutical waste generator to use it without submitting a petition or notice to the MPCA, as long as they comply with these two conditions:

- follow the directions in the most up-to-date version of this fact sheet
  Note: Check for the most recent version of this fact sheet at http://www.pca.state.mn.us/publications/w-hw4-45b.pdf.
- ensure all the documentation used to evaluate the pharmaceutical wastes is either kept at the site where the wastes were generated or is accessible from that site

Alternate method

Assume a pharmaceutical waste is lethal if it either:

- has not been evaluated
- is contained in any of the six *Risk Criteria Groups* in Table 1 on the next page

If the pharmaceutical waste is not contained in any of the Risk Criteria Groups, you may assume it is not lethal without determining the LD_{50}.

Remember: Just because a waste is not lethal does not mean it is non-hazardous. You must still evaluate the waste for all the other characteristics and listings.

Table 1: Alternate Method Risk Criteria Groups

Carcinogen	A drug considered known or reasonably anticipated to be a human carcinogen in the most recent published Report on Carcinogens, published by the U.S. National Toxicology Program (NTP) biennially, every even-numbered year. The most recent Report on Carcinogens is available on the NTP website at 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 off-label for treatment of cancer, which acts by causing cell death or by significantly decreasing cell growth or reproduction.
Combination U/P-listed drug	An unused drug that has more than one active ingredient and at least one of the active ingredients is on the hazardous waste U-List or P-List; and spill residues from these drugs. The U-List is available in MPCA fact sheet #w-hw2-03 at http://www.pca.state.mn.us/publications/w-hw2-03.pdf. The P-List is available in MPCA fact sheet #w-hw2-02 at http://www.pca.state.mn.us/publications/w-hw2-02.pdf.
Endocrine disruptor	Human and animal hormone pharmaceutical wastes, including but not limited to: · amino acid-derived hormones and their synthetic analogues examples*:dopamine, serotonin, and thyroxine · protein or peptide hormones and their synthetic analogues examples*: insulin, oxytocin, and glucagon · steroid hormones and their synthetic analogues examples*: cortisol, progesterone, and vitamin D · fatty acid-derived hormones and their synthetic analogues examples*: prostaglandins, thromboxane, and leukotrienes ***Note:** Specific hormones given here are only examples. All hormone pharmaceuticals of each hormone type are considered lethal, not just the given examples. Exception: Epinephrine at 0.24% concentration or less is not considered a lethal hazardous waste even though it is a hormone. For more information about waste epinephrine regulation, see MPCA fact sheet #w-hw3-35, Regulatory Consensus on Health Care Issues, at: http://www.pca.state.mn.us/publications/w-hw3-35.pdf.
NIOSH hazardous drug	A drug considered hazardous in Appendix A of the most recent Update of the U.S. National Institute for Occupational Safety and Health's (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. The most recent Update is available on the NIOSH website at http://www.cdc.gov/niosh.
OSHA hazardous drug	A drug considered hazardous in Appendix VI:2-1 of the most recent Update of the U.S. Occupational Safety & Health Administration's (OSHA) Technical Manual, Directive TED 01-00-015. The most recent Directive is available on the OSHA website at http://www.osha.gov.

Even after you have evaluated a pharmaceutical as lethal using the alternate method, you may always further evaluate the waste by calculating its effective LD_{50} to try to show that it is non-lethal.

For more information about calculating a pharmaceutical waste's effective LD_{50}, or for guidance in evaluating wastes that are not pharmaceuticals, see MPCA fact sheet #w-hw2-05, The Lethality Characteristic at: http://www.pca.state.mn.us/publications/w-hw2-05.pdf.

Remember: Just because a waste is not lethal does not mean it necessarily is non-hazardous. You must still evaluate the waste for all the other characteristics and listings.

More information

Guidance and requirements in this fact sheet were compiled from Minnesota Rules, Chapter 7045, and incorporate regulatory interpretation decisions made by the MPCA on February 25, 2005; February 18, 2010; and December 1, 2014. To review Minnesota Rules, visit the Office of the Revisor of Statutes at https://www.revisor.mn.gov/pubs.

Your metropolitan county and the MPCA have staff available to answer waste management questions. For more information, contact your metropolitan county hazardous waste office or your nearest MPCA regional staff. For information about reducing your generation of pharmaceutical wastes, contact the Minnesota Technical Assistance Program (MnTAP). Report spills of hazardous waste immediately to the Minnesota Duty Officer.

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
Website	http://www.co.[county].mn.us

Minnesota Technical Assistance Program

Toll free	1-800-247-0015
Metro	612-624-1300
Website	http://www.mntap.umn.edu

Small Business Environmental Assistance

Toll free	1-800-657-3938
Metro	651-282-6143
Website	http://www.pca.state.mn.us/sbeap/

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
Website	http://www.pca.state.mn.us

Minnesota Duty Officer

Toll free	1-800-422-0798
Metro	651-649-5451