

FS No. 37-077-1120

MANAGEMENT OF USED AND UNUSED INSULIN

BACKGROUND

M-cresol, also known as meta-cresol and 3-methylphenol, is a methyl substituted phenol used as a preservative in insulin. The insulin may be administered to patients by injection, insulin pens, pump, or through an intravenous (IV). M-cresol is a chemical that appears on the Resource Conservation Recovery Act list of hazardous constituents that can cause a waste to be classified as a toxic characteristic hazardous waste, U.S. Environmental Protection Act (EPA) Waste Code D024, if it exceeds the regulatory limit of 200 parts per million (ppm).

Based on the information gathered from a review of Safety Data Sheets of the most commonly identified insulin brand names (NovoLog[®], Novolin[®] R, Novolin N, Novolin 70/30, Lantus[®], Humalog[®], QuickPen[®]), the concentration of m-cresol preservative in the insulin solutions ranges from 0.17 % to 0.3%. This equates to 1,700 to 3,000 ppm, exceeding the 200 ppm regulatory level for a toxic hazardous waste. Insulin prepared for an IV bag and mixed at a 1:1 ratio of insulin to diluents would also exceed the 200 ppm regulatory level with a concentration ranging from 850 to 1,500 ppm.

MANAGEMENT OF USED INSULIN

- Pens and sharps (syringes) used to inject insulin must be placed in sharps containers and managed as regulated medical waste.
- Partially used vials that contain some amount of insulin and can no longer be used on patients are required to be managed and disposed as a hazardous waste.
- Empty used vials that contain no residual insulin may be disposed as solid waste.
- Partially used IV bags, which contain some amount of insulin, must be managed as a hazardous waste.
- Empty IV bags and tubing may be disposed as solid waste.

Contact the supporting installation Environmental Office for guidance on establishing an accumulation area for the HW items.

MANAGEMENT OF UNUSED INSULIN

Returning unused stock of insulin to a pharmaceutical reverse distributor will depend, in part, on whether or not a state has adopted the Management Standards for Hazardous Waste Pharmaceuticals final rule (found in Title 40 Code of Federal Regulations, Part 266, Subpart P). If a state has adopted the rule, the unused insulin must then meet the definition of a *Potentially Creditable Hazardous Waste Pharmaceutical (PCHWP)*. This means that the unused insulin must be undispensed, in the original manufacturer's container and less than 1 year expired.

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Use of trademarked name(s) does not imply endorsement by the U.S. Army
but is intended only to assist in identification of a specific product.

If the insulin does not meet the PCHWP definition, then it must be managed and disposed as a hazardous waste pharmaceutical; it may not be returned to a pharmaceutical reverse distributor.

Refer to the following EPA Website to determine whether your state has adopted the rule:
<https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>.

ASSISTANCE

Contact U.S. Army Public Health Center, Environmental Health Sciences Division at 410-436-3651 or usarmy.apg.medcom-aphc.mbx.hmwp@mail.mil for additional assistance.
