

Pharmaceutical Waste

Pharmaceutical Waste Defined

Pharmaceutical waste encompasses a diverse group of chemicals including, but not limited to, prescription and over-the-counter human drugs, veterinary drugs, diagnostic agents, and nutritional supplements. These items could be expired, damaged or simply unusable for any reason.

The California Department of Public Health (CDPH) recommends utilizing a reverse distributor for expired pharmaceuticals. Only pharmaceutical waste that falls under the Federal Conservation and Recovery Act (RCRA) of 1976, as amended (42 USCA Sec. 6901 et seq.) should be disposed of into a hazardous waste container. This includes P-listed, U-listed, and characteristic wastes. All remaining pharmaceutical waste that does not fall under the definition of RCRA waste (i.e. California non-RCRA) should be disposed of into a pharmaceutical waste container. Pharmaceutical waste generated in California must be treated by incineration, or by using an alternative treatment technology that has received approval from CDPH.

P-listed Wastes Used in Pharmaceuticals

P-listed wastes are characterized as being acutely hazardous and having an oral lethal dose of 50 mg/kg (LD50) or less. LD50 is the amount of a material, given all at once, which causes the death of 50% of a group of test animals.

40 CFR Part 261.33(e)

Constituent of Concern	Waste Code	Constituent of Concern	Waste Code
Arsenic trioxide	P012	Phentermine (CIV)	P046
Epinephrine base	P042	Physostigmine	P204
Nicotine	P075	Physostigmine salicylate	P1888
Nitroglycerin	P081	Warfarin >0.3%	P001

Note: Arsenic trioxide is used as a chemotherapy agent.

Disposing of Drugs Containing a P-listed Constituent

Pharmaceuticals must be disposed of as hazardous waste if the both of the following conditions are met: (1) the discarded drug waste contains a **sole active ingredient** that appears on the P List, and (2) **it has not been used for its intended purpose**. The second condition includes the drug and its associated container or dispensing instrument.

40 CFR Part 261.33

Example: A portion of an IV infusion was given to a patient, so the unused portion would be disposed of as hazardous waste.

Single Exception – Epinephrine

After giving a proper dose of epinephrine, any remaining residue or excess is considered to have been used for its intended use.

U-listed Wastes Used in Pharmaceuticals

Pharmaceuticals containing one or more of these constituents must be disposed of as hazardous waste, as the two conditions listed for P-listed wastes also apply to U-listed wastes.

40 CFR Part 261.33(f)

Constituent of Concern	Waste Code	Constituent of Concern	Waste Code
Chloral hydrate (CIV)	U034	Paraldehyde (CIV)	U182
<i>Chlorambucil</i>	U035	Phenol	U188
<i>Cyclophosphamide</i>	U058	Reserpine	U200
<i>Daunomycin</i>	U059	Resorcinol	U201
Dichlorodifluoromethane	U075	Saccharin	U202
<i>Diethylstilbestrol</i>	U089	Selenium Sulfide	U205
Hexachlorophene	U132	<i>Steptozotocin</i>	U206
Lindane	U129	Trichloromonofluoromethane	U121
<i>Melphalan</i>	U150	<i>Uracil mustard</i>	U237
Mercury	U151	Warfarin <0.3%	U248
<i>Mitomycin C</i>	U010		

Note: *Chlorambucil, Cyclophosphamide, Daunomycin, Diethylstilbestrol, Melphalan, Mitomycin C, Steptozotocin, and Uracil mustard* are used as chemotherapy agents.

Characteristic Hazardous Waste

A waste is considered hazardous under RCRA if it possesses at least one of the following measurable properties or characteristics:

1. **Ignitability (D001)** - waste presents a fire hazard under routine storage, disposal, and transportation or is capable of exacerbating a fire once it has started

Ignitable Properties	Resources	Ignitable Drug Formulations
Aqueous drug formulations contain 24% or more alcohol by volume and has a flashpoint of less than 140 degrees Fahrenheit (60 degrees Celsius).	<ul style="list-style-type: none"> o Safety Data Sheets (SDS) o Common pharmacy references such as Facts and Comparisons or their on-line database, E-Facts 	<ul style="list-style-type: none"> o Erythromycin Gel 2% o Texacort Solution 1% o Taxol Injection
Non-aqueous liquid formulations containing less than 24% alcohol, with a flashpoint of less than 140 degrees Fahrenheit (60 degrees Celsius).	<ul style="list-style-type: none"> o Safety Data Sheets (SDS) o Standard laboratory test procedure for measuring flashpoint 	<ul style="list-style-type: none"> o Flexible collodion used as a base in wart removers is not an aqueous solution and has a flashpoint of 45 degrees Celsius
Oxidizers or materials that	<ul style="list-style-type: none"> o 40 CFR 264 Appendix V 	<ul style="list-style-type: none"> o Bulk chemicals found in

readily supply oxygen to a reaction in the absence of air as defined by the Department of Transportation (DOT).	<ul style="list-style-type: none"> ○ Examples of Potentially Incompatible Waste Group 6-A Oxidizers ○ Possible ORM-D Consumer Commodity exclusion in 49 CFR 173.151 for small packages 	the compounding section of the pharmacy such as potassium permanganate
Flammable aerosol propellants meeting the DOT definition of a compressed gas.	<ul style="list-style-type: none"> ○ Possible ORM-D Consumer Commodity exclusion in 49 CFR 173.306 	○ Primatene aerosol

2. **Corrosivity (D002)**– waste that has a pH of less than or equal to 2 (highly acidic) or greater than or equal to 12.5 (highly basic)
3. **Reactivity (D003)** – waste is unstable under “normal” conditions and may cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water
4. **Toxicity (Multiple D Codes)** – waste that may fail the Toxicity Characteristic Leaching Procedure (TCLP) test due to heavy metals or chemicals

Ingredient	Waste Code	Regulator Level (mg/l)	Drugs Formulations Containing These Ingredients
Arsenic	D004	5.0	Arsenic trioxide (also P-listed)
Barium	D005	100.0	Barium sulfate (used in radiology)
Cadmium	D006	1.0	Multiple mineral preparations
Chloroform	D022	6.0	No longer commonly used
Chromium	D007	5.0	Multiple mineral preparations
Lindane	D013	0.4	Treatment of lice, scabies (also U-listed)
M-cresol	D024	200.0	Preservative in human insulins
Mercury	D009	0.2	Vaccines with thimerosal, eye, ear, preparations
Selenium	D010	1.0	Dandruff shampoo, multiple mineral preparations
Silver	D011	5.0	Silver sulfadiazine cream

List of Controlled Substances

To view a list of controlled substances compiled by the United States Drug Enforcement Administration (DEA), please click here: [List of Controlled Substances](#)

For additional guidance on pharmaceutical waste, please visit:

<https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx>