

# The Toxicity Characteristic: CALIFORNIA VS FEDERAL

By  
Leon Wirschem DEH-HMD  
[Leon.wirschem@sdcounty.ca.gov](mailto:Leon.wirschem@sdcounty.ca.gov)

&  
Steve Koester - SFSFR  
[stevekoester@santafesprings.org](mailto:stevekoester@santafesprings.org)





## ALL "HAZARDOUS WASTES" ARE BASED ON 4 TYPES OF HAZARDS

HAZARDOUS WASTE	
FEDERAL LAW PROHIBITS IMPROPER DISPOSAL. IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY AUTHORITY OR THE U.S. ENVIRONMENTAL PROTECTION AGENCY OR THE CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCE CONTROL.	
GENERATOR INFORMATION:	
NAME _____	PHONE _____
ADDRESS _____	CITY _____ STATE _____ ZIP _____
EPA ID NO. / MANIFEST NO. _____	EPA ACCUMULATION _____
CA. WASTE NO. _____	START DATE _____
CONTENTS COMPOSITION:	
PHYSICAL STATE: <input type="checkbox"/> SOLID <input type="checkbox"/> LIQUID	HAZARDOUS PROPERTIES: <input type="checkbox"/> FLAMMABLE <input type="checkbox"/> TOXIC
<input type="checkbox"/> CORROSIVE <input type="checkbox"/> REACTIVITY <input type="checkbox"/> OTHER _____	
EPA T. PROPER SHIPPING NAME AND UN OR NA NO. WITH PREFIX _____	
<b>HANDLE WITH CARE!</b>	





### TWO TYPES OF TOXICITY


A composite image for a slide titled "TWO TYPES OF TOXICITY". On the left is a black and white photograph of several dead fish floating in a body of water. On the right is a cartoon drawing of a fish with a sad, downturned mouth and wide, worried eyes.

### Acute Toxicity- Acute Hazardous Waste

- ◆ Federal regulations list Acutely Hazardous Waste in the P-List, 261.33
- ◆ State regulations list Acutely Hazardous Waste in the P-List, 66261.33
- ◆ Most of the "Listed" wastes are regulated due to their toxicity.

### FEDERAL TOXICITY CHARACTERISTIC

- ◆ Based only on Chronic Toxicity from the Safe Drinking Water Standards set in the 1970's
- ◆ Eight metals
- ◆ Four pesticides
- ◆ Two herbicides
- ◆ Twenty six organic compounds
- ◆ Listed as D004 to D043 Waste ID Codes

A small photograph showing several glasses and a pitcher filled with water, representing drinking water samples.

### The TCLP

- ◆ Solid/liquid samples are separated, the solids are processed and then re-combined with the liquid portion for analysis.
- ◆ Uses acetic acid for a leaching agent
- ◆ 20 parts acid to 1 part sample
- ◆ Put into a tumbler for 18 hours
- ◆ Then filtered and the leachate is analyzed (solids are discarded)

### TEST RESULTS

- ◆ The test results are compared to the numbers listed in Table I of CCR, Title 22 66261.24 as the Regulatory Level Mg/l.
- ◆ Equal to or greater than makes the waste material a RCRA Hazardous Waste

## 22CCR Table I Thresholds



EPA Hazardous Waste Number	Contaminant	Chemical Abstracts Service Number	Regulatory Level Mgf
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	26-23-5	0.5
D020	Chlordane	108-90-7	0.03
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0
D023	o-Cresol	95-48-7	200.0 <sup>1</sup>
D024	m-Cresol	108-39-4	200.0 <sup>1</sup>
D025	p-Cresol	106-44-5	200.0 <sup>1</sup>
D026	Cresol		200.0 <sup>1</sup>
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	1.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.13
D030	2,4-Dibromobenzene	131-14-2	0.13
D012	Dieldrin	72-29-8	0.02
D051	Heptachlor (and its epoxide)	76-44-8	0.008
D052	Hexachlorobenzene	118-74-1	0.13
D053	Hexachlorobutadiene	87-68-3	0.5
D054	Hexachlorocyclopentadiene	87-72-1	3.0
D008	Lead	7439-92-1	3.0
D013	Lindane	58-89-9	0.4
D009	Mercury	7439-97-6	0.2
D014	Methoxychlor	78-43-3	10.0
D055	Methyl ethyl ketone	78-93-3	200.0
D006	Nitrobenzene	98-95-3	2.0
D007	Para-chlorophenol	87-86-5	100.0
D008	Pyridine	110-86-1	5.0 <sup>1</sup>
D010	Selenium	7782-49-2	1.0
D011	Silver	7440-22-4	5.0
D009	Tetraachloroethylene	127-18-4	0.7
D015	Toxaphene	8001-35-2	0.5
D040	Trichloroethylene	79-01-6	0.5
D041	2,4,5-Trichlorophenol	95-95-4	400.0
D042	2,4,6-Trichlorophenol	88-06-2	2.0
D017	2,4,5-TP (Silver)	93-72-1	1.0
D043	Vinyl chloride	75-01-4	0.2

## Federally Regulated Metals

- ◆ Arsenic
- ◆ Barium
- ◆ Cadmium
- ◆ Chromium
- ◆ Lead
- ◆ Mercury
- ◆ Selenium
- ◆ Silver

## California



## SB 1966- CA hazardous waste pharmaceuticals transferred from DTSC to DHS (DPH)



State of California—Health and Human Services Agency  
Department of Health Services



DANA M. BONTA, R.N., Dr. P.H.  
Director

GRAY DAVIS  
Governor

October 15, 2002

To: Directors of Environmental Health  
Medical Waste Program Managers

SUBJECT: MANAGEMENT OF PHARMACEUTICAL MEDICAL WASTE

During 1996, Senate Bill 1966 was signed into law. This bill redirected regulation of California only hazardous pharmaceutical waste from the California Department of Toxic Substances Control (DTSC) to the California Department of Health Services (DHS). This change in the law did not affect pharmaceutical waste characterized as hazardous waste or as solid waste; only those pharmaceuticals characterized as "California only hazardous waste." Although this change redirected the disposal of the California only portion of this waste stream, it did not change the method of classifying the waste, which remained with DTSC. The language of the bill has often been considered unclear and it is frequently misunderstood. Therefore compliance and enforcement of the handling of the "new medical waste" comprised of "California Only" pharmaceuticals have been mired in confusion. Characterizing the waste to determine whether it was medical waste, hazardous waste or solid waste has been at the core of the confusion.

## Hazardous Waste or Medical Waste?

Pharmaceutical wastes that meet California's definition of hazardous waste, but not RCRA's definition, as well as pharmaceutical wastes generated by people who are not regulated under RCRA, are subject to the Medical Waste Management Act (Division 104, Part 14 California Health and Safety Code).

## CA Toxicity – 22 CCR 66261.24

- ◆ 20 Metals/Inorganics (Table II)
- ◆ 18 Persistent/Bioaccumulative Toxic Substances (Table III)
- ◆ Oral LD<sub>50</sub> less than 2,500mg/kg
- ◆ Dermal LD<sub>50</sub> less than 4,300 mg/kg
- ◆ Inhalation LC<sub>50</sub> less than 10,000 ppm
- ◆ 96 hour Aquatic Bioassay
- ◆ 0.001% weight listed constituents (16 OSHA carcinogens)
- ◆ Been shown to cause hazards to health/env.

## CA's Version of Toxic Constituents

- ◆ Table II of 66261.24(a) for metals and inorganics
- ◆ Table III of 66261.24(a) for bio-accumulative or persistent organics
- ◆ Both tables have a liquid threshold and a solid threshold for being a hazardous waste

## 22CCR Tables II and III- Thresholds

Substance <sup>a,b</sup>	STLC mg/l	TTLC Wei-Weight mg/kg
Antimony and/or antimony compounds	15	500
Arsenic and/or arsenic compounds	5.0	500
Asbestos		1.0 (as percent)
Barium and/or barium compounds (excluding barite)	100	10,000 <sup>c</sup>
Beryllium and/or beryllium compounds	0.75	75
Cadmium and/or cadmium compounds	1.0	100
Chromium (VI) compounds	5	500
Chromium and/or chromium (III) compounds	5 <sup>d</sup>	2,500
Cobalt and/or cobalt compounds	80	8,000
Copper and/or copper compounds: Fluoride salts		
Lead and/or lead compounds		
Mercury and/or mercury compounds		
Molybdenum and/or molybdenum compounds		
Nickel and/or nickel compounds		
Silver and/or silver compounds		
Thallium and/or thallium compounds		
Vanadium and/or vanadium compounds		
Zinc and/or zinc compounds		

(B) Table III - List of Organic Persistent and Bioaccumulative Toxic Substances and Their Soluble Threshold Limit Concentration (STLC) and Total Threshold Limit Concentration (TTLC) Values:

Substance	STLC mg/l	TTLC Wei-Weight mg/kg
Aldrin	0.14	1.4
Chlordane	0.25	2.5
DDT, DDE, DDD	0.1	1.0
2,4-Dichlorophenoxyacetic acid	10	100
Dieldrin	0.8	8.0
Dioxin (2,3,7,8-TCDD)	0.001	0.01
Etozin	0.02	0.2
Heptachlor	0.47	4.7
Kepon	2.1	21
Lead compounds, organic	0.4	4.0
Lindane	10	100
Methoxychlor	2.1	21
Nitex	1.7	17
Pentachlorophenol	5.0	50
Polychlorinated biphenyls (PCBs)	0.5	5
Toxaphene	204	2,040
Trichroethylene	1.0	10
2,4,5-Trichlorophenoxypropionic acid		

## CA Replaces TCLP with the TTLC & the STLC (WET Test)

- ◆ TTLC = Total Threshold Limit Concentration
- ◆ No sample dilution and doesn't consider landfill conditions
- ◆ STLC = Soluble Threshold Limit Concentration (WET Test)
- ◆ Same concept as the TCLP, but uses a different acid and digests for a greater time.

## State WET Procedure

- ◆ Uses procedure from 22CCR Div.4.5, CH.11, Appendix II
- ◆ Used for 19 inorganics and 18 organics
- ◆ Solids milled to 0.45 microns
- ◆ Diluted 10:1 with citric acid (sodium citrate) solution
- ◆ Leaching period is 48 hours
- ◆ Leachate is analyzed

## State Regulated Metals

- ◆ Antimony (CA)
- ◆ Arsenic
- ◆ Barium
- ◆ Beryllium (CA)
- ◆ Cadmium
- ◆ Chromium
- ◆ Cobalt (CA)
- ◆ Copper (CA)
- ◆ Lead
- ◆ Mercury
- ◆ Molybdenum (CA)
- ◆ Nickel (CA)
- ◆ Selenium
- ◆ Silver
- ◆ Thallium (CA)
- ◆ Vanadium (CA)
- ◆ Zinc (CA)



\* Fluoride salts & asbestos are also listed

## Solid Waste Determination Cont.

- ◆ If the results of the STLC are below the numbers listed in Table II and Table III, then the waste is not a hazardous waste for toxicity per CCR 66261.23(a)(1) and (2).
- ◆ However, in CA there are still 6 more criteria to go!!!!!!

### TCLP Vs STLC (Lead Example)

- |                                      |                                      |
|--------------------------------------|--------------------------------------|
| ◆ Federal TCLP                       | ◆ State STLC                         |
| ◆ Solid waste with 100 mg/kg of lead | ◆ Solid waste with 100 mg/kg of lead |
| ◆ 50 % leaches (Acetic Acid)         | ◆ 50 % leaches (Citric Acid)         |
| ◆ 20 to 1 dilution                   | ◆ 10 to 1 dilution                   |
| ◆ 50 mg/L divided by 20              | ◆ 50 mg/L divided by 10              |
| ◆ Test results = 2.5mg/L             | ◆ Test results = 5mg/L               |
| ◆ <b>Not a Hazardous Waste</b>       | ◆ <b>A Non RCRA Hazardous Waste</b>  |

### Criteria #3: Lethal Dose - Ingestion

- ◆ LD<sub>50</sub> = Less than 2500 mg/kg



### Criteria #4: Lethal Dose - Dermal

- ◆ LD<sub>50</sub> = Acute toxicity of less than 4300mg/kg



### Criteria #5: Lethal Concentration - Inhalation

- ◆ LC<sub>50</sub> = less than 10,000 ppm of gas or vapors



### Criteria #6: Acute Aquatic Toxicity

- ◆ LC<sub>50</sub> = Less than 500 mg/L within 96 hours



### Test Protocol: CA F&G/DHS 1988

- ◆ 20 fish tested, 10 per tank
- ◆ Checked every 24 hours
- ◆ Test tanks are 10 liters
- ◆ Fish are not fed during the test
- ◆ Equal number of fish for the control
- ◆ Three types of fish can be used for the test

## Rainbow Trout



## Golden Shiner



## Fathead Minnow



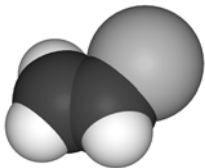
Fathead minnows crowd into a section of pipe.

## Proposed Test Species

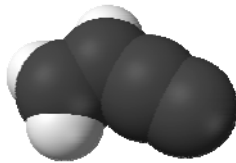


## Criteria #7: 0.001% Weight Listed Concentration

- ◆ Consists of 16 chemicals, most you have never heard of. Two examples are:



Vinyl Chloride



Acrylonitrile

## Criteria #8: Been Shown to Pose A Hazard to the Environment



## 22 CCR 66261.24(a)(8)

- ◆ Been shown through experience or testing to pose a hazard due to carcinogenicity, acute toxicity, chronic toxicity or bioaccumulative properties or persistence in the environment.

## DTSC To Create Regulations

- ◆ CHSC 25141.5(b) states that the Department must determine by **regulation** that the "waste's" Classification is likely to have broad application beyond the producer.
- ◆ In my opinion (not legal advice), this basically **eliminates** the requirement of 66261.24(a)(8) for the generator in making a waste determination

## DEMONSTRATION



## Useful References

- ◆ Sax's Dangerous Properties of Industrial Materials
- ◆ Hawley's Condensed Chemical Dictionary
- ◆ NIOSH Pocket Guide
- ◆ Merck Index
- ◆ Richard Lewis's Hazardous Chemicals Desk Reference
- ◆ ITI's Toxic and Hazardous Industrial Chemical Safety Manual
- ◆ [http://ccelearn.csus.edu/wasteclass/intro/intro\\_01.html](http://ccelearn.csus.edu/wasteclass/intro/intro_01.html)



## HAZARDOUS WASTE DETERMINATION FOR NON-RCRA HAZARDOUS WASTE TOXICITY Characteristic- 66261.24

Calculated oral or dermal toxicity =

$$\sum_{x=1}^n \frac{\%A_x}{TA_x}$$

%  $A_x$  is the weight percent of each toxic compound in the mixture.  
 $TA_x$  is the acute oral or dermal LD50 or acute oral LDLO of each component.

$\sum_{x=1}^n$  is the summation of the calculations, by ingredient

## Calculating Toxicity

<http://www.sdcounty.ca.gov/deh/hazmat/pdf/hm-9267.pdf>

- 1) Determine active ingredient: Active ingredients are acetaminophen 500 mg and diphenhydramine HCL 25 mg.
- 2) Determine toxicity:

$$\frac{100}{\left(\frac{\% \text{ chemical \#1}}{\text{LD50 or LDLO chem. \#1}}\right) + \left(\frac{\% \text{ chemical \#2}}{\text{LD50 or LDLO chem. \#2}}\right) + \left(\frac{\% \text{ chemical \#3}}{\text{LD50 or LDLO chem. \#3}}\right)}$$

	<i>Active ingredient</i>		Reference Source
	Diphenhydramine HCL	Acetaminophen	
Rat Oral LD50 <i>Toxicity</i>	500 mg/kg	N/A	MSDS
	500 mg/kg	N/A	Merck Index
	500 mg/kg	2400 mg/kg	RTECS

Dermal Toxicity: No data was available

### Calculating Toxicity

3) Since the toxicity is less than the established oral LD50 threshold of 2500 mg/kg, determine the weight % of each active component in the waste pharmaceutical: Manufacturer states the caplet has an average weight of 645mg.

Acetaminophen  $500/645 = 77.5\% \text{ by weight.}$   
 Diphenhydramine HCL  $25 / 645 = 3.8\% \text{ by weight.}$

4) Calculate oral or dermal toxicity =

$$\frac{77.5}{2400} + \frac{3.8}{500} = 0.0323 + 0.0076 = 0.0399 = 2,506.27 \text{ mg/kg}$$

The calculated oral toxicity is greater than the established oral LD50 threshold of 2500 mg/kg; therefore this waste pharmaceutical is NOT a non-RCRA hazardous waste.

### California- Extremely Hazardous Waste (66261.110, 66261.113)

- ◆ Acute oral LD50 less than or equal to 50 mg/kg
- ◆ Acute dermal LD50  $\leq$  43 mg/kg
- ◆ Acute inhalation LC50  $\leq$  100 ppm gas/vapor
- ◆ Contains any of the 16 listed carcinogens at a concentration of 0.1% by weight
- ◆ Exposure may likely result in death...
- ◆ Is water reactive
- ◆ Exceeds listed value in 66261.113
- ◆ These criteria are generally 100x more toxic than the values listed in 66261.24 (50x for oral toxicity)
- ◆ EHW pharmaceuticals that are CA only wastes are regulated as Medical Waste.

### HW TOXICITY RE-CAP

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>◆ <b>FED TOXICITY</b></li> <li>◆ List of 40 elements and chemicals</li> <li>◆ Uses TCLP for solids</li> <li>◆ No actual characteristic criteria</li> </ul> | <ul style="list-style-type: none"> <li>◆ <b>CA TOXICITY</b></li> <li>◆ Additional metals and organics</li> <li>◆ 7 Additional Criteria for Toxicity</li> <li>◆ Use Appendix X in 22 CCR 66261 as a guide for potential toxicity.</li> </ul> |
|---|---|

Vizzier in his earlier years teaching SW-846 Sampling

