The Toxicity Characteristic: CALIFORNIA VS FEDERAL

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With "special" guest
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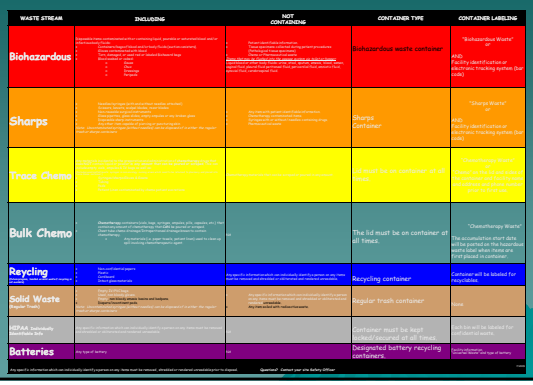
Have you seen something like this?

This is a sample chart only. Source: *www.h2e-online.org/docs/h2epharmablueprint41506.pdf*

Or this?



WASTE STREAM	INCLUDING	NOT CONTAINING	CONTAINER TYPE	CONTAINER LABELING
Biohazardous	Disposable items contaminated or containing liquid, parenteral or secretions/blood and/or other potentially infectious: - Contaminated liquid (blood and/or body fluids but not secretions) - Items saturated with liquid or secretions - Items dripping or capable of being dripped but not saturated - Blood models or other - Blood - Urine - Stool - Discharge - Sputum - Tissue	Human identifiable information - Patient specimens or other items during patient procedures - Items with Protected Health Information - Items in Pharmaceutical waste **Items that are not saturated with liquid or secretions or contain no potentially infectious material are not biohazardous and should be placed in regular trash.**	Biohazardous waste container	"Biohazardous Waste" or AND Facility identification or electronic tracking system (bar code)
Sharps	Needles for injection (including blood sampling, IV Sets) Syringes with or without needles Needle/syringe combinations Glass pipettes, glass slides, and/or capsules or any broken glass Razor blades, scalpels, and/or lancets Sharp items capable of puncturing or cutting regular Sharp items that have been in contact with the diagnosis of a patient the regular trash or sharps container	Any items with human identifiable information Chemotherapy or chemotherapy items Pharmaceutical waste containing drugs Pharmaceuticals	Sharps Container	"Sharps Waste" or AND Facility identification or electronic tracking system (bar code)
Trace Chemo	Chemotherapy items that are not saturated with liquid - Empty vials - Empty syringes - Empty IV bags - Empty containers - Empty tubing - Empty pharmaceutical containers	Any items with human identifiable information Chemotherapy or chemotherapy items Pharmaceutical waste containing drugs Pharmaceuticals	Lid must be on container at all times.	"Chemotherapy Waste" or Name on the container and the date of the initial accumulation must be on the container.
Bulk Chemo	Chemotherapy containers (vials, bags, syringes, ampules, pills, capsules, etc.) that contain any amount of chemotherapy. Items can be poured or scraped. Items that are saturated with liquid or secretions containing chemotherapy - Chemotherapy - Any chemotherapy (i.e. paper towels, gauze pads) used to clean up spill involving chemotherapeutic agent	Any items with human identifiable information	The lid must be on container at all times.	"Chemotherapy Waste" The accumulation start date will be posted on the hazardous waste label when items are first placed in container.
Recycling	Paper and board of paper Glass Metal Plastic Electronic goods (cell phones, etc.)	Any specific information/medium can individually identify a person or any items that are hazardous or biohazardous and cannot be recycled.	Recycling container	Container will be labeled for recyclables.
Solid Waste (Regular Trash)	Paper products Food **non-biohazardous items and bandages** **Empty/cleaned bottles and cans** Items that are not saturated with liquid or secretions and are not a part of a patient the regular trash or sharps container	Any specific information/medium can individually identify a person or any items that are hazardous or biohazardous and cannot be recycled. **ANYTHING** **Anything soaked with medical/biohazardous**	Regular trash container	None
HIPAA Individually Identifiable Info	Any specific information which can individually identify a person or any items must be removed, shredded or rendered unreadable prior to disposal		Container must be kept locked/closed at all times.	Each box will be labeled for confidential waste.
Batteries	Any type of battery	All	Designated battery recycling containers.	Battery information Original Waste Stream type of battery

Any specific information which can individually identify a person or any items must be removed, shredded or rendered unreadable prior to disposal. Questions? Contact your site Safety Officer

ALL “HAZARDOUS WASTES” ARE BASED ON 4 TYPES OF HAZARDS

Characteristic of Ignitability

- A liquid with a flash point less than 140 degrees F and not a aqueous solution of <24% alcohol.
- A solid capable of causing fire through friction, absorption of moisture or spontaneous chem. changes and burns vigorously to create a hazard.
- Ignitable gas as defined by 49 CFR 173.300.
- Oxidizer as defined in 49 CFR 173.151.

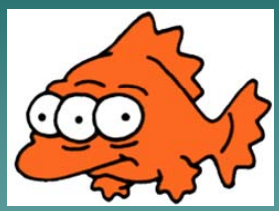
Characteristic of Corrosivity

- An aqueous liquid with a pH </= 2 or >/= 12.5
- A liquid that corrodes steel (SAE 1020) at a rate greater than 6.35 mm per year

Characteristic of Reactivity

- Normally unstable & violent change w/o detonation
- Reacts violently with water
- Forms explosive mixtures w/water
- Mixed w/water, forms toxic gases
- Cyanide or sulfide bearing waste that can generate toxic gases when mixed with non-corrosive liquids
- Capable of detonating under a strong initiating source or heat w/confinement
- Explosive under normal conditions
- Forbidden Explosive, Class A or Class B Explosive per DOT definition

TWO TYPES OF TOXICITY



RCRA Listed Waste Examples

Examples of products with a sole active ingredient contained on the P or U list

Listing	Active Ingredient	Examples
P042	Epinephrine	Injectables
P075	Nicotine and Salts	Chewing gum used to stop smoking
U002	Acetone	Solvent, nail polish remover
U010	Mitomycin C	Antineoplastic, chemotherapy
U035	Chlorambucil	Antineoplastic, chemotherapy
U044	Chloroform	Solvent, anesthetic
U058	Cyclophosphamide	Antineoplastic, chemotherapy
U089	Diethylstilbestrol	Antineoplastic, chemotherapy
U122	Formaldehyde	Preservative, disinfectant
U129	Lindane	Lice control spray, shampoos
U132	Hexachlorophene	Cleansers
U150	Melphalan	Antineoplastic, chemotherapy
U182	Paraldehyde	Sedative, DEA controlled
U188	Phenol	Throat sprays, mouthwash
U200	Reserpine	Antihypertensive
U210	Resorcinol	Keratolytic
U202	Saccharin and salts	Artificial sweeteners
U237	Uracil Mustard	Antineoplastic, chemotherapy
U248/P001	Warfarin and Salts	Anticoagulant

RCRA Characteristic Examples

D001	**Ignitable**	
	1. Aqueous based liquid with >24 % alcohol	Injectables, cough syrup, tinctures
	2. Non-aqueous liquid with flash point ≤ 140° F	Solvents, non-aqueous injectables
	3. Oxidizers	Whiteners, bleach, peroxides, nitrates
	4. Ignitable compressed gases	Aerosols with propane and/or isobutene
D002	**Corrosive**	
	Aqueous with pH ≤ 2.0 or ≥ 12.5	Acids, bases, depilatories, hydroxides
D003	**Reactive**	
	1. Reacts violently with water	Aerosols are the most common D003 waste.
	2. Generates toxic gases when mixed with water	
	3. Generates cyanide or sulfide bearing gases	
	4. Capable of explosive reaction if heated or under confinement	
	5. Normally unstable	
D004-D043	**Toxic -as determined by the Toxicity Characteristic Leaching Procedure (TCLP)**	

	Element of toxicity	TCLP	Examples of Products
D005	Barium	100mg/L	Enemas, colorings
D007	Chromium	5 mg/L	Vitamin/mineral supplements
D009	Mercury	0.2 mg/L	Colorings, nasal/hemorrhoidal/ophthalmic preps, vaccines and injectables. Present as thimerosal, phenyl mercuric nitrate or acetate
D010	Selenium	1 mg/L	Vitamin/mineral supplements, shampoo
D011	Silver	5 mg/L	Creams, applicators
D013	Lindane	0.4 mg/L	Creams, lotions, shampoo
D024	m-Cresol	200 mg/L	Some insulin and other injectables

FEDERAL TOXICITY CHARACTERISTIC

- Initially based on Chronic Toxicity from the Safe Drinking Water Standards set in the 1970's
- Eight metals
- Four pesticides
- Two herbicides

- Twenty six organic compounds (added in 1990)
- Listed as D004 to D043 Waste ID Codes

RCRA Toxicity Determination

- Liquids can be tested using any method as long as it has documented quality control
- By definition, liquids contain less than 0.5% solids
- Solids must go through a procedure that mimics landfill conditions called a **Toxic Characteristic Leaching Procedure** (TCLP) prior to testing.

The TCLP

- Promulgated in 1990 replacing the old EP (Extraction Procedure) Toxicity test
- 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 for toxicity

22CCR Table I Thresholds

EPA Hazardous Waste Number	Contaminant	Chemical Abstracts Service Number	Regulatory Level mg/l
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	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0
D023	o-Cresol	95-48-7	200.0 [FN1]
D024	m-Cresol	108-39-4	200.0 [FN1]
D025	p-Cresol	106-44-5	200.0 [FN1]
D026	Cresol		200.0 [FN1]
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7
D030	2,4-Dinitrotoluene	121-14-2	0.13
D012	Endrin	72-20-8	0.02
D031	Heptachlor (and its epoxide)	76-44-8	0.008
D032	Hexachlorobenzene	118-74-1	0.13
D033	Hexachlorobutadiene	87-68-3	0.5
D034	Hexachloroethane	67-72-1	3.0
D008	Lead	7439-92-1	5.0
D013	Lindane	58-89-9	0.4
D009	Mercury	7439-97-6	0.2
D014	Methoxychlor	72-43-5	10.0
D035	Methyl ethyl ketone	78-93-3	200.0
D036	Nitrobenzene	98-95-3	2.0
D037	Pentachlorophenol	87-86-5	100.0
D038	Pyridine	110-86-1	5.0 [FN2]
D010	Selenium	7782-49-2	1.0
D011	Silver	7440-22-4	5.0
D039	Tetrachloroethylene	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 (Silvex)	93-72-1	1.0
D043	Vinyl chloride	75-01-4	0.2

Federally Regulated Metals

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

Callllllifornnnnia

CA Toxicity – 22 CCR 66261.24

- 20 Metals/Inorganics (Table II)
- 18 Persistent/Bioaccumulative Toxic Substances (Table III)
- Oral LD_{50} less than 2,500mg/kg
- Dermal LD_{50} less than 4,300 mg/kg
- Inhalation LC_{50} less than 10,000 ppm
- 96 hour Aquatic Bioassay
- 0.001% weight listed constituents (16 OSHA carcinogens)
- Been shown to cause hazards to health/environment

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

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 metals, 2 inorganics, asbestos, 10 pesticides and 10 other organics
- Solids milled to 0.45 microns
- Diluted 10:1 with 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

Procedures For Waste Determination of Solids w/Metals

- Always run the TTLC first
- See if results are > TTLC levels, if yes it is at least a CA Haz Waste

Solid Waste Determination (Cont.)

See if results are 20 times greater than Table I in CCR 66261.24
If yes, you must run a TCLP.
If no,

Solid Waste Determination (Cont.)

- If results are less than the TTLC numbers, see if they are greater than 10 times the STLC numbers in Table II and Table III, if yes, you must run a STLC

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
- Solid waste with 100 mg/kg of lead
- 50 % leaches
- 20 to 1 dilution
- 50 mg/L divided by 20
- Test results = 2.5mg/L
- **Not a Hazardous Waste**

- State STLC
- Solid waste with 100 mg/kg of lead
- 50 % leaches
- 10 to 1 dilution
- 50 mg/L divided by 10
- Test results = 5mg/L
- **A Non RCRA Hazardous Waste**

EXERCISE

Criteria #3: Lethal Dose - Ingestion

- LD_{50} = Less than 2500 mg/kg

LD_{50} Examples - Rat

- Nicotine = 50 mg/kg
- Caffeine = 192 mg/kg
- Table Salt = 3,000 mg/kg
- Grain Alcohol = 7,060 mg/kg
- Vitamin C = 11,900 mg/kg

DEMONSTRATION

Criteria #4: Lethal Dose - Dermal

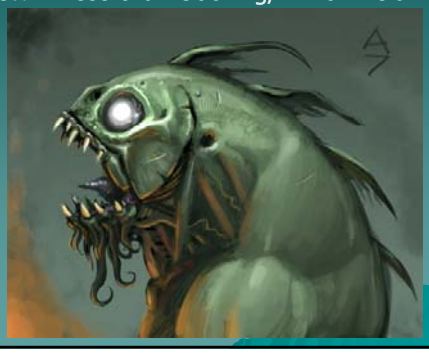
- LD_{50} = Acute toxicity of less than 4300mg/kg

Criteria #5: Lethal Concentration - Inhalation

- LD_{50} = less than 10,000 ppm of gas or vapors

Criteria #6: Acute Aquatic Toxicity

- LC_{50} = 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

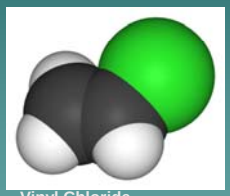
Not “Golden Shriner”

Fathead Minnow

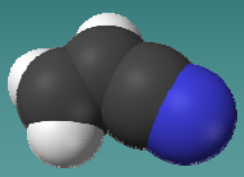
Proposed Test Species (PETA)

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.
- Basically **eliminates** the requirement of 66261.24(a)(8) for the generator in making a waste determination, however…
- Other laws & regulatiosns apply to carcinogens. Be responsible.

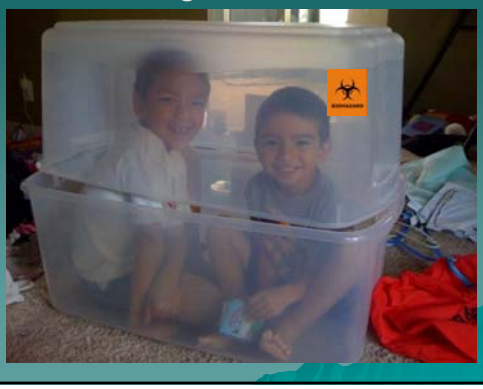
HW TOXICITY RE-CAP

- **FED TOXICITY**
- List of 40 elements and chemicals
- Uses TCLP for solids
- No actual characteristic criteria

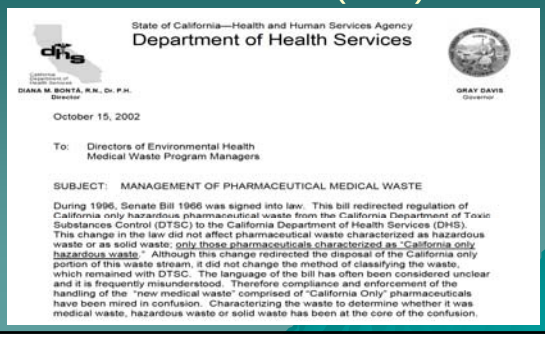
- **CA TOXICITY**
- 7 Additional Criteria for Toxicity
- Use Appendix X in 22 CCR 66261 as a guide for potential toxicity.

Why so many containers?

Protecting Our Children



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



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

DIANA M. BONTÁ, R.N., Dr. P.H.
Director

GRAY DAVIS
Governor

October 15, 2002

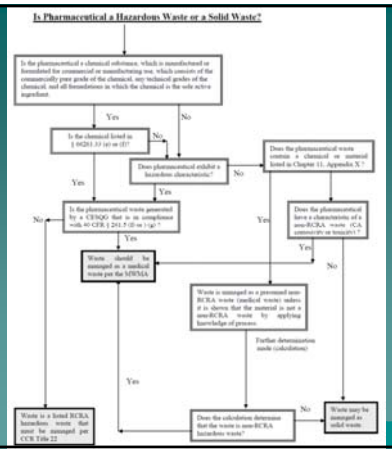
To: Directors of Environmental Health
Medical Waste Program Managers

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).



Some examples of Non-RCRA Wastes

Wastes hazardous due to:

- Aquatic Toxicity- e.g. 1% propofol
- Orally Toxic- LD50 <2500 mg/kg
- Dermally Toxic- LD50 <4300 mg/kg
- Toxic by inhalation- LD50 <10K mg/kg
- Trace Chemo
- CA regulation of Commercial Chemical Products sent for recycling
- Listed chemicals in RCRA empty (but not CA empty) containers
- RCRA listed wastes properly managed by a CESQG

Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

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

Calculated oral or dermal toxicity =

$$\sum_{X=1}^{n} \frac{\%Ax}{TAx}$$

% 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:

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

	Active ingredient		Reference Source
	Diphenhydramine HCL	Acetaminophen	
Rat Oral LD50 *Toxicity*	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 % by weight,
Diphenhydramine HCL 25 / 645 = 3.8 % by weight.

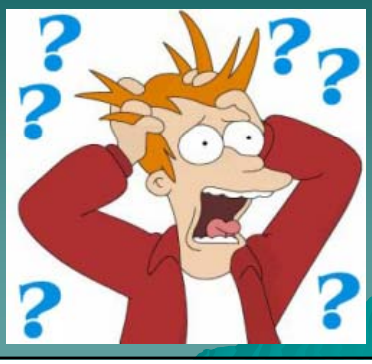
4) Calculate oral or dermal toxicity =

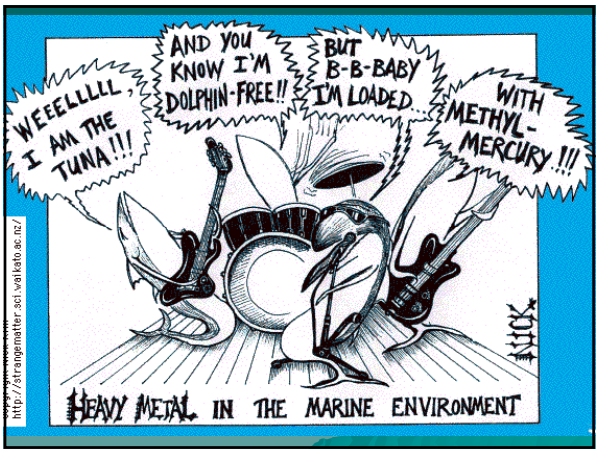
$$\frac{100}{\frac{77.5}{2400} + \frac{3.8}{500}} = 2{,}506.27\ \text{mg/kg}$$

$$= 0.0323 + 0.0076 = 0.0399$$

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

QUESTIONS - COMMENTS





Useful Resources

- 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

Sources of Information

- The Toxicity Characteristic; Steve Koester, presented at the California CUPA Conference
- Management of Pharmaceutical Medical Waste Memorandum; October 15, 2002; California Department of Health Services
- DTSC & Cal EPA http://ccelearn.csus.edu/wasteclass/intro/intro_01.html
- Managing Pharmaceutical Waste; *Brandi Starjack, County of Ventura, Environmental Health Division* and Maryam Sedghi, County of San Diego, Department of Environmental Health Hazardous Materials Division
- Various San Diego County EH&S professionals
- H2e-online.org