



U.S. Department  
of Transportation

**Pipeline and  
Hazardous Materials Safety  
Administration**

400 Seventh Street, S.W.  
Washington, D.C. 20590

JUN 29 2005

Mr. Terry Grimmond  
Clinical Director  
Daniels Sharpsmart, Inc.  
3 Tarbett Road Hillcrest  
Hamilton 2001, New Zealand

Reference No. 04-0279

Dear Mr. Grimmond:

This is in response to your letter and electronic mail concerning how to classify and transport chemotherapeutic and pharmaceutical wastes under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). We paraphrased your questions and answered them in the order provided. We apologize for the delay in responding and any inconvenience this may have caused.

Question 1. What hazard classes are chemotherapeutic and pharmaceutical wastes?

Answer 1. The hazard class assigned to a material is based on its chemical composition, concentration of ingredients, and hazard characteristics. Under § 173.22 of the HMR, the shipper is responsible for determining if a material meets the definition of a hazard class, assigning the material an appropriate proper shipping name, and selecting the appropriate package, markings, and labels. Sometimes, more than one proper shipping name from the Hazardous Materials Table (HMT; § 172.101) may describe the same material. For example, a shipper may assign a waste chemotherapy drug that meets the definition of a Division 6.1 (poison) hazard class the generic proper shipping description "Waste Medicine, solid, toxic, n.o.s., 6.1, UN 3249, PG II," or "Waste Toxic solids, organic, n.o.s., 6.1, UN 2811, PG II," or, if applicable, assign it a proper shipping description based on a specific chemical name.

For your reference, § 171.8 defines a hazardous waste to mean a waste material that is subject to the Uniform Hazardous Waste Manifest (UHW) requirements of the U.S. Environmental Protection Agency specified in 40 CFR Part 262. A waste that does not require completion of a UHW is not considered a "hazardous waste" for purposes of the HMR and is not subject to the HMR unless it meets the definition of a hazardous material under the HMR. Further, when a shipper chooses a proper shipping name, the accompanying information for that entry on the HMT must be used in its entirety and may not be interchanged with that of any other entry. If a material does not meet the definition of a HMR hazard class, and it is not a hazardous waste, hazardous substance, or marine pollutant, it is not regulated as a hazardous material under the HMR.



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173.197 (d)(1)(vi)

Question 2. What UN numbers apply to chemotherapeutic and pharmaceutical wastes? Neither term is assigned a UN number in Column 4 of the HMT. Does this mean these materials are not hazardous under the Department of Transportation's regulations? The UN numbers on the HMT do mention "Medicine liquid, toxic, n.o.s., 6.1, UN 1851, PG II or III" and "Medicine, solid, toxic, n.o.s., 6.1, UN 3249, PG II or III."

Answer 2. The same answer as in A1.

Question 3. If chemotherapeutic and/or pharmaceutical wastes are mixed with Division 6.2 (infectious) sharps, does the Division 6.2 hazard class take precedence? In discussions with Ms. Eileen Edmonson of your staff, she said Division 6.2 takes precedence over chemotherapeutic and pharmaceutical waste and referred to § 173.197(d)(3)(vi).

Answer 3. Section 173.2a specifies how to classify a material having more than one hazard under the HMR. Under § 173.2a(c)(3), a material that meets the definition of a Division 6.2 hazard class and another hazard class, which may include a limited quantity Class 7 material but no other type of Class 7 material, must be classed as Division 6.2.

Question 4. If chemotherapeutic and/or pharmaceutical wastes are mixed with Division 6.2 sharps, are neither Division 6.1 or Division 6.2 labels required if a BIOHAZARD marking is present on the sharps container?

Answer 4. Sections 172.400 and 172.402(a) require the outside of each package containing a hazardous material to be labeled as specified for the material in the HMT, including those for the subsidiary hazard class if applicable. The HMR include an exception from labeling in § 173.134(c)(1) for "Regulated medical waste, 6.2 (infectious), UN 3291, PG II" (RMW) transported by a private or contract carrier in a non-specification, rigid, non-bulk package conforming to §§ 173.24 and 173.24a, and 29 CFR 1910.1030. If a package of RMW meets the requirements of the exception, a shipper may place the BIOHAZARD marking conforming to 29 CFR 1910.1030, and shown in § 172.323, on the outside of the package in place of the INFECTIOUS SUBSTANCE label shown in § 173.432. To qualify for this exception, § 173.134(c)(1)(ii) requires that the package not contain a waste culture or stock of a Division 6.2 material. Further, § 173.134(d) requires that a Division 6.2 material listed in the exceptions under §§ 173.134(b) and (c) that also meets the definition of another hazard class, or that is a hazardous substance, hazardous waste, or marine pollutant comply with the applicable requirements of the HMR for each hazard class it contains, which include, if applicable, placing the Division 6.1 label on the outside of the package.

I hope this information is helpful.

Sincerely,



Hattie L. Mitchell, Chief  
Regulatory Review and Reinvention  
Office of Hazardous Materials Standards

**Drakeford, Carolyn**

**From:** Edmonson, Eileen  
**Sent:** Monday, December 13, 2004 3:23 PM  
**To:** Drakeford, Carolyn  
**Subject:** FW: Chemo and Pharma waste

*Edmonson  
§173.197(d)(1)(vi)  
Regulated Medical  
Waste  
04-0279*

Carolyn – Can you please log this in as the new Terry Grimmond letter and assign it to me? He withdrew the one he submitted under reference no. 04-0127.

Thanks,

Eileen

-----Original Message-----

**From:** Terry Grimmond [mailto:terry.grimmond@sharpsmart.com]  
**Sent:** Thursday, December 09, 2004 7:27 PM  
**To:** eileen.edmonson@rspa.dot.gov  
**Subject:** Chemo and Pharma waste

Hi Eileen,

I hope your Thanksgiving was excellent and Christmas preparations are not too hectic. I'm back in NZ for a while and going over discussions we had during my Nov visit. May I seek clarification on Chemotherapeutic and Pharmaceutical waste.

**Q1. What Hazard Class are Chemo and Pharma wastes?**

When either of these terms is used to search CFR49, very little comes up. They are not included in definitions. There is a hint in **CFR49 §173.197(d)(1)(vi)** that Chemo may be in either Class 6.1 or 7 (my understanding of Class 7 is that it is exclusively for Radioactive items). Pharmaceutical waste is not mentioned at all.

**Q2. What UN number do Chemo and Pharma waste attract?**

Neither term is mentioned in UN List - does this mean they are not hazardous under DOT regulations? The UN List does mention UN 1851 (Medicine Liquid, Toxic, NOS) and UN3249 (Medicine Solid, Toxic, NOS)

**Q3. If Chemo and/or Pharma waste is mixed with Class 6.2 sharps, does 6.2 take precedence?**

In our discussions you said 6.2 takes precedence over Chemo and Pharma waste, and referred to para 173.197 d)3)vi. When I read this para I cannot see a "precedence" ruling. (perhaps I wrote wrong para reference). 173.197 d)3)(vi) Division 6.1 or Class 7 chemotherapeutic waste, untreated cultures and stocks of infectious substances containing Risk Group 2 or 3 pathogenic organisms, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as provided by paragraph (d)(3)(v) of this section.

**Q4. If Chemo and/or Pharma waste is mixed with Class 6.2 sharps, neither Class 6.1 nor Class 6.2 labels are required if a biohazard label is present on the sharps container.**

You stated that every hazard class must be represented on label but Susan Gorsky's reply to me of Nov 14 2003 (03-0265) (last para) infers this is negated if a biohazard label is present.

Kind regards,

Terry

Terry Grimmond

12/14/2004

Clinical Director  
Daniels SharpSmart Inc