



U.S. Department  
of Transportation  
**Research and  
Special Programs  
Administration**

NOV 14 2003

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

Ms. Terry Grimmond  
Clinical Director  
The Daniels Corporation  
3 Tarbett Rd Hillcrest  
Hamilton 2001, New Zealand

Ref. No.: 03-0265

Dear Ms. Grimmond:

This responds to your inquiry of October 20, 2003, regarding Regulated Medical Wastes (RMW) and labeling of sharps containers in accordance with the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

Your company produces a reusable sharps container that has passed UN requirements for certification as a primary transport container (although the sharps container is collected and transported from hospitals in a large, dedicated secondary container on wheels). Your company currently supplies hospitals in the United States with these containers, and it is your understanding that the United States has adopted the international requirements for shipping infectious substances. You ask about marking and labeling requirements for the sharps containers.

We recently revised the requirements in the HMR for infectious substances, including sharps meeting the definition of RMW, to harmonize them with international standards and incorporate several RMW exemptions (67 FR 53118, August 14, 2002; Docket HM-226). Certain of these revised requirements refer to the Food and Drug Administration's (FDA) requirements for sharps containers, and the FDA is the lead agency in approving single-use and reusable medical devices, such as sharps containers. The HMR do not supersede these requirements. For more information on the FDA's requirements, you may wish to contact Ms. Diane Goldsberry or Ms. Carolyn Niebauer of the FDA's Centers for Devices and Radiological Health, Office of Compliance, Division of Enforcement, General Hospital Devices Branch, HFZ-333, 2094 Gaither Road, Rockville, MD, 20850, at 301-594-4618.

Sharps containers used as inner packagings in bulk packagings used to transport RMW must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the bulk packaging originates at a single location and is delivered to a single location (see § 173.197(e)). If intended for reuse, a sharps container must be approved by FDA as a medical device for reuse and must be permanently marked for reuse (see § 173.197(e)(3)). Sharps containers used as inner packagings in bulk packagings used to transport RMW need not be labeled with a Division 6.2 (INFECTIOUS SUBSTANCES) label or a BIOHAZARD label. However, the outer bulk packaging must be marked with a BIOHAZARD marking that conforms to the requirements in § 172.323 and with the UN



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173.197

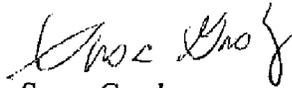
identification number (UN 3291) in accordance with § 172.302.

For non-bulk shipments, a sharps container must be puncture-resistant for sharps and sharps with residual fluids as demonstrated by conducting the performance tests in Subpart M of Part 178 of the HMR. A sharps container that conforms to the DOT or UN performance requirements must be marked as indicated in § 178.503(f). For shipments of sharps that meet the definition for RMW, the sharps container must be marked "Regulated Medical Waste, UN 3291" and with the name and address of the consignor or consignee (see § 172.301(a) and (d)). The container must be labeled with a Division 6.2 (infectious substances) label. Only one label is required to be displayed on a non-bulk packaging in association with the proper shipping name. When transported by a private or contract carrier, RMW, including sharps, in a non-bulk package is excepted from the requirement for a Division 6.2 label if it is marked with a "BIOHAZARD" marking in accordance with regulations of the Occupational Safety and Health Administration at 29 CFR 1910.1030 (see § 173.134(c)).

A Division 6.1 (POISON) label is not authorized under the HMR for packages containing RMW.

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,



Susan Gorsky  
Senior Transportation Regulations Specialist  
Office of Hazardous Materials Standards

**Gorsky, Susan**

**From:** Cushmac, George  
**Sent:** Monday, October 20, 2003 8:03 AM  
**To:** Gorsky, Susan  
**Cc:** 'terry@daniels.com.au'; Cushmac, George  
**Subject:** FW: Labelling sharps containers

*Engrum  
§ 173.197  
Regulated Medical Waste  
03-0265*

Susan,

Per our conversation earlier this morning, I am forwarding a question from Terry Grimmond regarding DOT requirements for the labelling of sharps containers (see e-mail message below). Please respond directly to Mr. Grimmond.

Thanks,

George

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

**From:** Terry Grimmond [mailto:Terry@daniels.com.au]  
**Sent:** Friday, October 17, 2003 4:48 PM  
**To:** Cushmac, George  
**Subject:** Labelling sharps containers

Dear Dr Cushmac,  
Don Burger suggested I put my Q to you. I am enquiring re DOT requirements for the labelling of sharps containers.

My company produces a reusable sharps container that has passed UN requirements for certification as a primary transport container (although it is collected and transported from hospitals in a large, dedicated secondary container on wheels. We are currently supplying hospitals in USA and I note DOT's move to UN TDG requirements.

- Q1. What must be shown on a sharps container label? (ie, is the UN biohazard diamond compulsory in USA; is "UN 3291" compulsory?)  
Q2. For the use of reusable sharps containers for disposal of chemotherapeutic sharps waste, what must be shown on a sharps container label? (ie, is the UN biohazard diamond used in USA or should it be the skull & Crossbones 6.1 diamond? Or both?).  
Q3. If diamonds are required, are they required on opposite sides of the container?

I have read the DOT regs fairly thoroughly but cannot see where small container labelling is covered.

Kind regards,

*Terry Grimmond*

*Clinical Director, The Daniels Corporation*

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10/20/03