



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

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

NOV 17 2004

Mr. Hussein
Director QA/Operations
LSL Industries, Inc.
5535 N. Wolcott Avenue
Chicago, IL 60640

Ref. No. 04-0253

Dear Mr. Hussain:

This is in response to your letter dated October 26, 2004, and subsequent conversation with a member of my staff, regarding the small quantity exception in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically you ask if "Disposable Kits" for hospitals qualify for the small quantity exception in § 173.4.

You describe two "Disposable Kits" in your letter:

- (1) The first (IV Start kit #1) contains several non-hazardous materials, and 0.67 ml of Chlorhexidine Gluconate 2% in 70% Isopropyl Alcohol, which you have classified as "Isopropyl alcohol solution, 3, UN1219, PG II."
- (2) The second kit (IV Start kit #2) has the same configuration as the first; however, it contains 1.5 ml of the isopropyl alcohol solution.

Both of these kits meet the quantity limitation in § 173.4(a)(1)(i) of 30 ml per inner receptacle for Class 3 (Flammable) liquids. Assuming they meet the additional requirements of § 173.4, and the outside of each package is marked with the statement, "This package conforms to 49 CFR 173.4," the "Disposable Kits" you described are excepted from any other requirements of the HMR.

I hope this information is helpful. Please contact us if you require additional assistance.

Sincerely,



John A. Gale
Chief, Standards Development
Office of Hazardous Materials Standards



040253

172.101
173.4

Eichenlaub
§172.101
§173.4
Labeling
04-0253

LSL Industries, Inc.

Manufacturers of Quality Medical Devices & Disposable Kits

October 26, 2004

Office of Hazardous Material
Standard Research Special
U.S Department of Transportation
400 Seventh Street
South West Washington. D.C 20590-0001
Attn: DHM-10

Re: Verification of Shipping Classification

Dear Sir/Madam,

I am writing to you to seek your help in properly deciding any labeling requirements of our shipping package. We are a small Manufacturer of Disposable Kits for the Hospitals. Recently one of our customers enquired about labeling of a product IV Start Kits under DOT Regulation. For example the configuration of the IV Start kit # 1 is as follows:

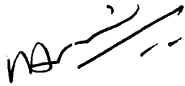
1. IV Dressing (thin film to cover IV site)
2. Gauze (Cotton)
3. Chlorhexidine Gluconate 2% in 70% Isopropyl Alcohol (Antiseptic ampule 0.67 ml)
4. Tourniquet
5. Tape
6. Label

IV Start kit # 2 has the same configuration except it contains 1.5 ml Chlorhexidine Gluconate 2% in 70% Isopropyl Alcohol. These components are packed together in a small Tyvek and moisture proof plastic pouch. 100 of these individually packaged kits are then further packed in a small carton weighing about 6 pounds. Considering the above configuration with only 0.67 ml and 1.5 ml of antiseptic in each individual kit, we are interested in knowing the DOT labeling requirements applicable, if any, for shipping our product. Our interpretation of CFR 49& REF: 173.4 are that this product may be exempted for ORM-D labeling requirements under the small quantity clause.

Page 2
DOT

We respectfully request you to kindly verify our interpretation. If there is any regulation applicable for labeling we will be glad to implement immediately. If you have any questions as you review this request, please feel free to call me at 773-878-1100. Thank you very much for your kind consideration and favorable action.

Sincerely,

A handwritten signature in black ink, appearing to be 'V. Hussain', with a long horizontal stroke extending to the right.

V. Hussain
Director QA/Operations