



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

JAN 2 2003

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

Mr. Jeff Henderson
RCS, Inc. - Ohio
950 Taylor Station Road
Gahanna, OH 43230

Reference No.: 02-0309

Dear Mr. Henderson:

This is in response to your letter concerning the exceptions for Consumer commodities, ORM-D, under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if your products, Intravenous starting kits and Dressing change kits, that contain an alcohol pad and/or an iodine/alcohol swab may be shipped as Consumer commodity, ORM-D. You state that the swabs contain 2 to 10 mL of alcohol or alcohol and iodine solution and are packaged in a hermetically sealed pouch. The pouch contains free liquid when manufactured. These products are shipped to hospitals and health care facilities.

In general terms, a consumer commodity, as defined in 49 CFR 171.8, is a material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. The definition includes materials that are suitable for retail sale even if not specifically so intended and which may, in fact, be used in some other fashion. It is the opinion of this office that the Intravenous starting kits and Dressing change kits would qualify for shipment as "Consumer commodity, ORM-D."

I hope this satisfies your request.

Sincerely,

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



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§171.8(c)



November 26, 2002

Consumer Commodity
02-0309

Research and Special Programs Administration
400 7th Street SW
DHM-10

Washington D.C. 20590-0001

Attn: Edward Mazzullo-Director of the Office of Hazardous Materials Standards

RE: Letter of Interpretation under the Consumer Commodity Definition

Dear Mr. Mazzullo,

The following requests a letter of interpretation regarding the applicability of the definition of a Consumer Commodity as stated in 49 CFR 171.8. RCS, Inc.'s client, Becton Dickinson, manufactures and ships medical products. The products, requesting interpretation, are Intravenous (IV) Starting Kits and Dressing Change Kits, which contain an Alcohol pad and/or an Iodine/Alcohol Swab. These products are shipped to hospitals and health care facilities for patient care purposes.

Alcohol and Iodine Swabs consist of 2 ml to 10 ml of alcohol or alcohol and iodine solution. The swabs are packaged in a hermetically sealed pouch and contain free liquid when manufactured. These products are regarded by the FDA as being Generally Regarded as Safe and Effective (GRASE) under the Tentative Final Monograph for Health-care Antiseptic Drug Products.

Dressing Change Kits and IV Starting Kits are prepackaged products for specialized use in changing patient dressing or starting an IV. Within the prepackaged kits are Alcohol or Alcohol and Iodine Swabs identical to those outlined above. IV Start Kits are packaged in a thick plastic pouch and sealed with a Tyvek lid to maintain sterility and prevent breakage during transport or handling. Dress Change Kits are packaged in rigid plastic trays and sealed with a plastic pouch to prevent breakage during transportation and handling.

A letter of interpretation is requested to allow for shipment of the above products as Consumer Commodity, ORM-D materials. While the above products are manufactured and intended for clinical use, the type of packaging utilized for the products can be suitable in household use or personal care.

Under the current definition, a *Consumer Commodity means a material that is packaged and distributed in a form intended or suitable for sale through retail*

sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. This term also includes drugs and medicines.

It is the opinion of Becton Dickinson and RCS, Inc. that the above mentioned products can be classified as Consumer Commodity, ORM-D materials. Therefore, it is requested that a letter of interpretation be formed to acknowledge if the above products may be shipped as a Consumer Commodity, ORM-D materials.

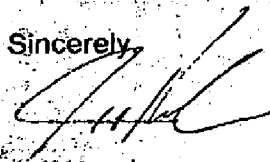
Additional information regarding the above products can be obtained from the following sources:

Rand Pugmire
Becton Dickinson
9450 South State St.
Sandy, UT 84070
Phone: 801-565-2550
Fax: 801-565-2749

Jeff Henderson
RCS, Inc.
950 Taylor Station Rd, St M
Gahanna, OH 43230
Phone: 614-552-8530 x 31
Fax: 614-552-8541

Upon determination and completion of a letter of interpretation, please fax and send a hard copy to the above fax numbers and addresses. Your cooperation and timeliness is greatly appreciated.

Sincerely,



Jeff Henderson
Technical Consultant
RCS, Inc.