U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

FEB 1 4 2013

Mr. Robert J. Ten Eyck
Director, Technical Services
TEN-E Packaging Services, Inc.
1666 County Road 74
Newport, MN 55055

Reference No. 12-0260

Dear Mr. Ten Eyck:

This is in response to your November 12, 2012 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the definition of an "aerosol." In your letter, you describe a microfoam delivery system that consists of two separate 300 ml (10.25 ounces) canisters, one that contains "UN 1072, Oxygen, compressed, 2.2 (non-flammable compressed gas), 5.1 (oxidizer)" under 5.4 bars of pressure and the other that contains a foaming product that does not meet the definition of a Department of Transportation hazard class and "UN 1013, Carbon dioxide, 2.2" under 1.2 bars of pressure. You also state these canisters are joined together with a protective collar equipped with a safety clip and a packaging system that allows the two canisters to be twisted together, the oxygen dispensed into the canister with the foaming product, and the pressurized foaming product to be released at the time of use through the use of manometer tubing and syringe. You ask whether the microfoam delivery system meets the definition of an "aerosol."

The answer is no. The HMR defines an aerosol as "any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, the sole purpose of which is to expel a nonpoisonous (other than a Division 6.1 Packing Group III material) liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas" (see § 171.8). Based on the information you provided, the canister that contains the foaming product and carbon dioxide meets the definition of an aerosol after it has been charged with oxygen from the other canister, and this occurs when both canisters are no longer in transportation. While in transport, the canister that contains the foaming product is not under sufficient pressure at 1.2 bars of pressure to allow its product to be expelled. Further, the canister containing 300 ml of oxygen exceeds the 4 ounce capacity limit under

§ 173.306(a)(1) that would allow it to be transported as a limited quantity. Therefore, it is the opinion of this Office that the canister containing the foaming product is not regulated as a hazardous material under the HMR, and the canister that contains the oxygen must be described as "UN 2037, Receptacles, small, containing gas (gas cartridges), 2.2, 5.1" or "UN 1072, Oxygen, compressed, 2.2."

I hope this satisfies your request.

Sincerely,

T. Glenn Foster

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

TEN-E

TEN-E Packaging Services, Inc.

November 12, 2012

Edmonson
§171.8
§172.101
Definitions
12-0260

Charles Betts
Standards and Rulemaking, PHH-10
Office of Hazardous Materials Safety
U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
1200 New Jersey Avenue
S.E. Building, 2nd Floor
Washington, DC 20590

Dear Charles:

On behalf of the BTG International Group, TEN-E Packaging Services is seeking a formal interpretation on a unique medical product packaging that we believe should be properly described as an "Aerosol". The aerosol system consists of 300 ml canisters locked together with a dispensing device that incorporates a protective collar. The top canister contains oxygen under a pressure of 5.4 bar and the bottom unit contains product and carbon dioxide under a pressure of 1.2 bar. The oxygen is released into the bottom canister at the time of product dispensing to maintain the product's efficacy. The attached schematic clearly illustrates the packaging concept.

While generally aerosol packages combine both the propellant and product at the time of filling there have been newer developments such as the bag on valve package design where for quality purposes the propellant and product are separated. The design as presented in the attached schematic in essence follows the same concept in that the main propellant, the oxygen, is kept separate until the time of use. Since this package system is designed to expel a liquid under pressure we think that its classification as an aerosol is appropriate but would appreciate your input on this regulatory matter.

Per §105.30 of Title 49 CFR, TEN-E is requesting that the attached schematic be kept confidential due to the proprietary nature of the design.

Sincerely,

Robert J. Ten Eyck
Director, Technical Services
TEN-E Packaging Services, Inc.

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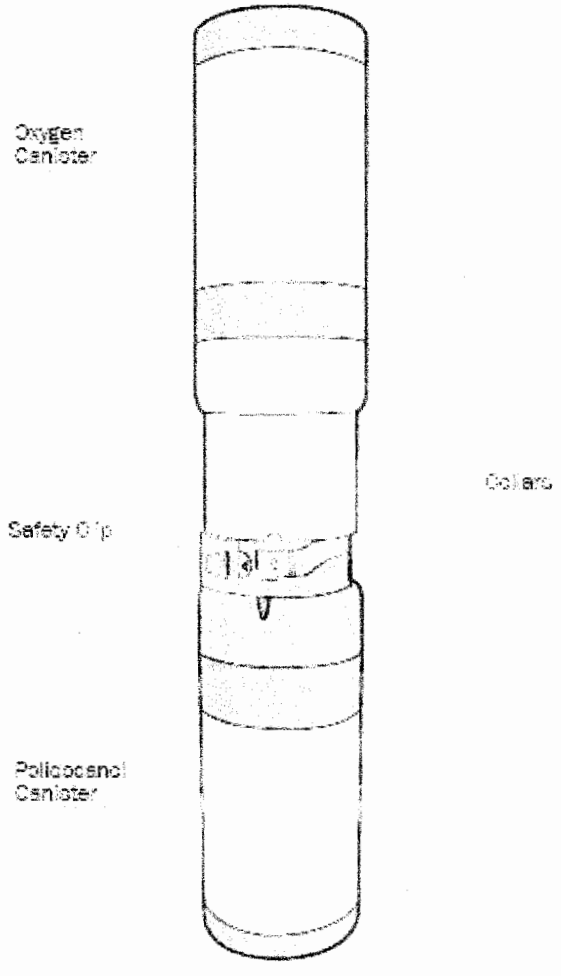
Unpacking

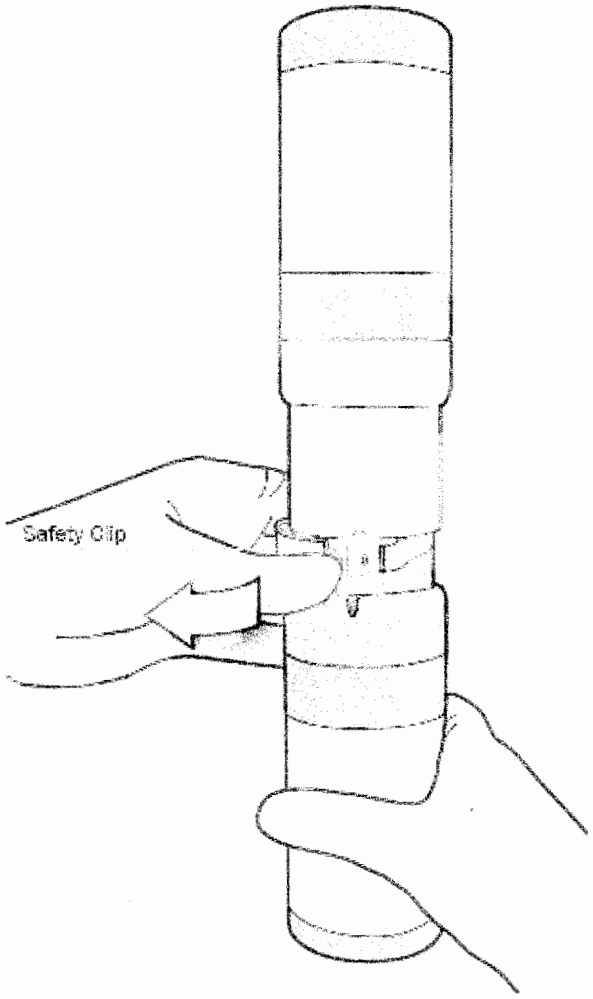
Open pouch using a pair of scissors. Place canisters upright on a clean stable surface with the white oxygen canister on top . Discard empty pouch.

Figure 2



Remove the safety clip by lifting one corner of the clip out . Discard the safety clip.

Figure 3



Gas Charging of the Polidocanol Canister

To begin the gas transfer, twist the canisters together clockwise until they come to a stop and the small indicators/marks on the collars are aligned . You may hear a bubbling sound. While the canisters are gassing, keep them upright on a clean flat surface for 1 minute. Use a timing device to keep track of the 1 minute time.

Figure 4

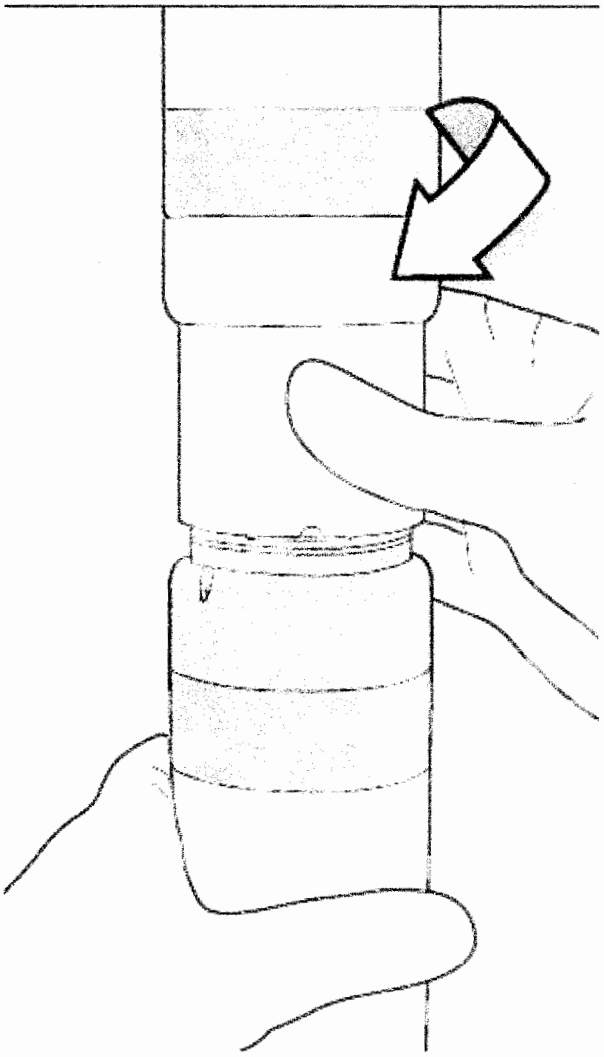


Figure 5