



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

MAY 15 1998

R. Sam Niedbala, Ph.D., BCFE
Executive Vice President
STC Technologies, Inc.
1745 Eaton Avenue
Bethlehem, Pennsylvania 18018

Dear Dr. Niedbala:

This responds to your letter of April 27, 1998, addressed to Mr. Edward Mazzullo, Director, Office of Hazardous Materials Standards, concerning limited quantity shipments of compressed gases. Specifically, you request confirmation that your Histofreezer® device qualifies to be shipped as a limited quantity under § 173.306 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

In your letter, you describe the Histofreezer® device as a metal canister containing 90 milliliters (3.16 oz.) of liquefied gas. The liquefied gas is a mixture consisting of 75 percent dimethyl ether and 25 percent propane.

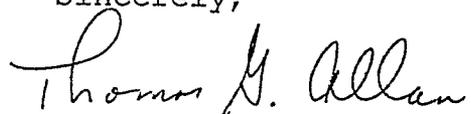
Your understanding is correct. The Histofreezer® device, consisting of a mixture of liquefied compressed gases in a container of not more than four fluid ounces capacity, meets the definition for a limited quantity under § 173.306(a)(1) of the HMR and is therefore exempt from specification packaging requirements and from labeling requirements except when offered for transportation by air.

You may also wish to take advantage of certain exceptions to the regulations available for shipments of consumer commodities. A consumer commodity, defined in § 171.8 of the HMR, 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. This definition includes drugs and medicines. Products that meet the definition of consumer commodity in § 171.8 and that conform to the packaging requirements of § 173.306 may be renamed "consumer commodity" and reclassified as ORM-D material. Packages of ORM-D material must be marked "Consumer Commodity, ORM-D" in accordance with § 172.316.

Shipments of ORM-D materials are not subject to the shipping paper requirements of Subpart C of Part 172 of the HMR unless the material meets the definition of a hazardous substance or hazardous waste or unless offered for transportation by air.

I hope this satisfies your request.

Sincerely,

A handwritten signature in cursive script that reads "Thomas G. Allan". The signature is written in dark ink and is positioned above the typed name.

Thomas G. Allan
Senior Transportation Regulations Specialist
Office of Hazardous Materials Standards



STC Technologies, Inc.

detection technologies for the next millennium

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173.306

April 27, 1998

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials
U.S. Department of Transportation
Research and Special Programs Administration
400 Seventh Street, S.W.
Washington, D.C. 20590

Re: Request for Exception from Hazardous Materials Shipping and Labeling Requirements for Histofreezer[®] Device

Dear Mr. Mazzullo:

In accordance with 49 CFR §173.306(a)(1) and for the reason stated herein, STC Technologies, Inc. requests an exception from the Hazardous Materials shipping and labeling requirements for Histofreezer[®] device, a product used for the removal of warts and benign skin lesions.

The Histofreezer[®] device is manufactured by Koninklijke Utermöhlen N.V., located in the Netherlands and is distributed in the U.S. solely by STC Technologies. The Histofreezer[®] device is composed of a metal canister containing 90 milliliters (3.16 oz.) of liquefied gas (75 percent dimethyl ether and 25 percent propane) and disposable 2 millimeter or 5 millimeter plastic foam tips that must be attached to the canister during usage. The device operates by saturating the tip of the applicator with the liquefied gas. As the liquefied gas evaporates from the bud, the applicator reaches a very low effective temperature thereby allowing the removal of warts or other lesions.

As noted above, the chemical composition of the Histofreezer[®] device includes a mixture of dimethyl ether and propane. As stated in 49 CFR §172.101, both substances are subject to packaging and labeling exceptions outlined in 49 CFR §173.306 for limited quantities of compressed gases. A limited quantity of compressed gas is defined by 49 CFR §173.306(a)(1), in which the compressed gas is packaged in "containers of not more than 4 fluid ounces capacity (7.22 cubic inches or less)..." Based on this definition, the Histofreezer[®] device as described above meets the requirements for limited quantities of compressed gases and should therefore be excepted from the Hazardous Materials packaging and labeling requirements specified in the regulations.

Your rapid review and response to this request is greatly appreciated. Please do not hesitate to contact me at (610)882-1820 if you have any questions or need additional information.

Sincerely,

R. Sam Niedbala, Ph.D., BCFE
Executive Vice President