



# Shipping Recommendations For PreservCyt™ Solution and CytoLyt™ Solution

(Effective 04/09/04)\*

## **A. Shipping PreservCyt Solution Only (such as from a lab to a physician)**

### **Domestic Ground Shipments - Limited Quantities:**

In the U.S., PreservCyt Solution is classified as a Class 3 Flammable liquid, assigned to Packing Group III (PG III).

U.S. Department of Transportation (DOT) regulations 49 CFR Parts 100-185 are referenced for domestic (U.S.) Shipments.

49 CFR 173.150 (Limited Quantities) allows PreservCyt Solution in vials to be shipped in Limited Quantities when shipped via ground transportation in a sturdy box. The total volume in a package cannot exceed 5 liters nor weigh more than 30 kg (66 lbs). Limited Quantities are exempt from hazard labeling requirements. The following are the domestic ground shipping recommendations:

- a. PreservCyt Solution must be shipped in the vials.
- b. Place the vials in a good quality cardboard box, such as the Cytyc box that holds 250 vials. Pack vials in a manner (adding protective packing material as necessary) as to limit movement of individual vials.
- c. Mark the package as "Flammable liquids, n.o.s., (Methanol Solution), 3, UN1993, Ltd. Qty." and add orientation arrows on the ends.
- d. Print "Flammable liquids, n.o.s., (Methanol Solution), 3, UN1993, PGIII, Ltd. Qty." on the Shipping papers.

### **Domestic Ground Shipments - Other than Limited Quantities:**

When shipping packages in excess of "Limited Quantity" amounts:

- e. Do not include "Ltd Qty" in the wording on the package or on the Shipping papers as indicated in c and d above.
- f. Affix a Class 3 "Flammable" hazard label to the outer package in close proximity of the wording described in "c" above. See the example of the label on the last page of these recommendations.

### **Domestic Air Shipments:**

In addition to a, c, d, e, and f above, the following are recommendations for domestic air shipments:

- g. Maximum allowable package sizes are:
  - i. Sixty (60) liters (3000-vials) for passenger aircraft, and
  - ii. Two hundred twenty (220) liters (11,000-vials) for cargo aircraft.
- h. Single packages containing more than sixty (60) liters (3000-vials) of total product must be clearly marked "FOR CARGO AIRCRAFT ONLY".
- i. The vials must be shipped in United Nations (UN) certified 4G packaging for any quantity in an aircraft. (E.g., the Cytyc PreservCyt Solution 250 vial box or equivalent.)
- j. A Class 3 "Flammable" label must be affixed to the outer package near the words "Flammable liquids, n.o.s., (Methanol Solution)".
- k. It is voluntary to place an "Air Eligibility" label (an airplane in a circle) adjacent to the words "Flammable liquids, n.o.s., (Methanol Solution)".

\*These instructions are Cytyc's interpretation of the various regulations as of the effective date; however, Cytyc will not be responsible for any non-conformance to the actual regulations.

# Shipping Recommendations For PreservCyt™ Solution and CytoLyt™ Solution

(Effective 04/09/04)\*

## All Domestic Shipments:

The following are recommendations for all domestic ground and air shipments:

- l. If the PreservCyt Solution is shipped in a package also containing non-hazardous material, the hazardous material must be listed first, or be printed in a contrasting color (or highlighted) to differentiate it from the non-hazardous material.
- m. The total quantity of PreservCyt Solution and the number of vials must appear on the Shipping papers.

## International Ground Shipments - Limited Quantities:

When shipping internationally, PreservCyt Solution is classified with a primary hazard of Class 3 (Flammable liquid), and with a secondary hazard of Class 6.1 (Toxic). It is assigned to PG III.

The reference used for the international ground recommendations is the *ADR - European Agreement Concerning the International Carriage of Dangerous Good by Road* (United Nations). A "Limited Quantity" is defined as a package containing a maximum net quantity of 5-liters and not weighing more than 20 kg (40 lbs). The recommendations for international ground shipments are as follows:

- a. PreservCyt Solution must be shipped in the vials.
- b. Place the vials in a good quality cardboard box, such as the Cytyc box that holds 250 vials. Pack vials in a manner (adding protective packing material as necessary) as to limit movement of individual vials.
- c. Mark the package with "Flammable liquids, toxic, n.o.s., (Methanol Solution), 3, 6.1, UN1992, PGIII Ltd. Qty" and add orientation arrows on the ends.
- d. The Shipping papers should include all the information indicated in "c" above.

## International Ground Shipments – Other than Limited Quantities:

- e. Do not include "Ltd Qty" in the wording on the package or on the Shipping papers as indicated in c and d above.
- f. Affix both a Class 3 "Flammable" label and a secondary Class 6.1 "Toxic" label to the package adjacent to the markings indicated in paragraph "c" above. Copies of the labels can be found on the last page of these recommendations.

## International Air Shipments:

The references used for the International Air recommendations are:

- International Civil Aviation Organization's (ICAO's) *Technical Instructions for the Safe Transport of Dangerous Goods by Air*,
- International Air Transport Association's (IATA's) *Dangerous Goods Regulations*

In addition to a, c, d, e, and f above, the following are the recommendations for international air shipments:

- g. Maximum allowable package sizes are:
  - i. Sixty (60) liters (3000-vials) for passenger aircraft, and
  - ii. Two hundred twenty (220) liters (11,000-vials) for cargo aircraft.
- h. Packages containing more than sixty (60) liters of product must be clearly marked "FOR CARGO AIRCRAFT ONLY"
- i. The vials must be shipped in United Nations (UN) certified 4G packaging for any quantity in an aircraft. (E.g., the Cytyc PreservCyt Solution 250 vial box or equivalent.) Pack vials in a manner (adding protective packing material as necessary) as to limit movement of individual vials.

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- j. Limited Quantity exemption can only be used if the package has a maximum net quantity of 2-liters.
- k. Packaging manufacturer's specifications markings are not required when shipping Limited Quantity.
- l. It is voluntary to place an "Air Eligibility" label (an airplane in a circle) adjacent to the words "Flammable liquids, toxic, n.o.s. (Methanol Solution)".
- m. When a "Cargo Aircraft Only" marking is required, it must be affixed on the same package surface and near the hazard labels.
- n. The shipper is responsible for the completion of a "Shipper's Declaration for Dangerous Goods" form.

### **B. Shipping PreservCyt Solution With Patient Sample (such as from a physician to a lab)**

Risk Group 1 samples are those, which contain pathogens under such conditions that their ability to produce disease is very low to none. An independent laboratory challenged PreservCyt Solution with a variety of microbial and viral organisms. The organisms became non-viable after 15-minutes in the solution. This challenge allows you to place a patient sample in PreservCyt Solution into the Risk Group 1 classification.

#### **Domestic (U.S.) Shipments:**

Follow the appropriate U.S. DOT regulations for shipping Risk Group 1 diagnostic specimens.

These regulations do not apply when the specimens are transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens.

#### **International Shipments:**

Follow the appropriate IATA, ADR, or country specific regulations for shipping Risk Group 1 diagnostic specimens.

### **C. Shipping CytoLyt Solution Only (such as from a lab to a physician)**

#### **Domestic Ground Shipments:**

CytoLyt Solution has a flash point of 109° F. For US ground transportation only, a Flammable liquid with a flashpoint at or above 100° F that does not meet the definition of any other hazard class may be reclassified as a Combustible liquid. As such, CytoLyt Solution, shipped via ground, is exempt from the requirements of the DOT Hazardous Materials Regulations.

#### **Domestic Air Shipments:**

When shipping CytoLyt Solution via air, follow the Domestic Air Shipments recommendations for Shipping PreservCyt Solution Only that can be found in section "A" of this document.

#### **International Ground and Air shipments:**

When shipping CytoLyt Solution via ground or air, follow the International Ground or Air Shipments recommendations for Shipping PreservCyt Solution Only that can be found in section "A" of this document.

### **D. Shipping CytoLyt Solution With Patient Sample (such as from a physician to a lab)**

CytoLyt Solution containing a patient sample falls into the Risk Group 2 classification. Risk Group 2 specimens have a moderate individual risk and low community risk.

#### **Domestic Shipments:**

Follow the appropriate U.S. DOT regulations for shipping Risk Group 2 diagnostic specimens.

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These regulations do not apply when the specimens are transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens

### International Shipments:

Follow the appropriate IATA, ADR, or country specific regulations for shipping Risk Group 2 diagnostic specimens.



Class 3 “Flammable” primary hazard label.



Class 6.1 “Toxic” secondary hazard label.

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