

TIP No. 036-0824 Shipping ThinPrep® Solutions and Samples within CONUS 51–500 Vials—Limited Quantity Shipments

PURPOSE.

This paper details transportation requirements when shipping ThinPrep[®] solutions and samples (51– 500 vials) within the Continental United States (CONUS) in Limited Quantity Shipments by Domestic Highway Transportation and Commercial Air. When shipping less than 51 vials, additional exceptions are allowed (see DCPH-A 2024). NOTE: If shipping greater than 500 vials per shipment, it is required to limit the contents of each package to a maximum of 500 vials to use the limited quantity exception allowed by the Department of Transportation and the International Air Transport Association (IATA) Dangerous Goods Regulation (DGR) (IATA 2024).

REFERENCES.

- Defense Centers for Public Health–Aberdeen (DCPH-A). 2024. Technical Information Paper (TIP) No. 035-0824, Shipping ThinPrep[®] Solutions and Samples within CONUS 1-50 Vials Small/Excepted Quantity Shipments by Highway and Commercial Air.
- DCPH-A. 2023. FS No. 023-0823, Management of Waste from the ThinPrep® Processor.
- International Air Transport Association (IATA). 2024. *Dangerous Goods Regulations*, 65th Edition. https://www.iata.org/en/publications/dgr/
- *Code of Federal Regulations,* "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans," Title 49, Part 172.
- *Code of Federal Regulations,* "Shippers—General Requirements for Shipments and Packagings," Title 49, Part 173.
- Department of Defense (DoD). 2014. Defense Transportation Regulation, 4500-9R, Part II, Cargo Movement. https://www.ustranscom.mil/

BACKGROUND.

DoD medical facilities collect and process specimens to test for cervical cancer using the ThinPrep PreservCyt[®] solution made by Hologic Inc. PreservCyt is a reagent grade, methanol-based, buffered preservative solution and is classified as a hazardous material (HM) due to its low flashpoint (80°F/26.5°C) and must be packaged and shipped according to regulatory requirements governing transport of HMs within the United States. A vial of ThinPrep contains 20 mL of methanol solution.

This TIP supersedes APHC Fact Sheet No. 37-039-0518

Approved for public release; distribution is unlimited.

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TRAINING.

Personnel who package any quantity of ThinPrep solution must receive training within 90 days of employment per 49 CFR 172.704 and the IATA DGR, Chapter 1, Section 1.5 (49 CFR 172; IATA 2024). All personnel who sign HM shipping papers for ThinPrep shipments must be formally trained per DoD Defense Transportation Regulation (DTR), 4500-9R, Part II, Chapter 204, Section D, which provides a list of DoD-approved schools (DoD 2014). Certification training can be obtained by successfully completing the Transport of Biomedical Material Course; DCPH-A provides this course and is the authorized proponent for this course (see DTR 4500-9R, Part II, Chapter 204, Section D(1)(d)). Registration for the TBM Course is available at http://ph.health.mil/Pages/Training.aspx. This TIP does not preclude the requirement for specialized training at an approved course for personnel HM shipping papers and should not be construed as a substitute for the specialized training required.

HAZARD CLASSIFICATION.

New vials of PreservCyt solution, as well as those containing a specimen, are classified as a Hazard Class 3, flammable liquid, based on the manufacturer's Safety Data Sheet (SDS). Although PreservCyt solution contains a biological specimen being shipped for purposes of diagnosis, the sample IS NOT classified as a Diagnostic Specimen. PreservCyt solution contains chemicals that neutralize any infectious agents that might be present; therefore, the specimen is excepted from being classified as a Division 6.2 infectious substance (material) based on 49 CFR Section 173.134(b)(4) or the IATA DGR, Chapter 3, Section 3.6.2.2.3.

BASIC SHIPPING DESCRIPTION.

The basic shipping description for 51–500 vials of ThinPrep solution when shipped domestically by highway or commercial air includes the United Nations (UN) Identification Number (ID), proper shipping name (followed by technical name), hazard class, and packing group designation, i.e., *UN1993, Flammable liquids, n.o.s. (contains methanol), 3, III*.

LIMITED QUANTITY SHIPMENT.

Limited quantity shipment requirements are defined in 49 CFR 172.101, Column 8A of the Hazardous Materials Table and the IATA DGR, Chapter 2, Section 2.7. New vials of PreservCyt solution or specimens collected in PreservCyt may be shipped as a limited quantity provided <u>each</u> inner receptacle (vial) does not contain more than 5 L of solution (49 CFR 172; IATA 2024). Each vial of ThinPrep holds 20 mL of solution.

SHIPPING SPECIFICATIONS.

Domestic Highway Transportation

The 49 CFR 172.101, *Hazardous Materials Table*, Column 8A (exceptions) specifies the appropriate section under 49 CFR Part 173 that determines the quantity limits and types of packaging that may be used to ship that particular HM as a limited quantity. The proper shipping name "Flammable liquids, n.o.s." lists three packing group (PG) designations (i.e., I, II, or III). Based on flash point properties

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provided by the SDS (80°F/26.5°C), ThinPrep is assigned to PG III. Column 8A of the *Hazardous Materials Table* identifies 49 CFR 173.150 for shipping limited quantities of Class 3 flammable liquids.

- **Packaging**: Combination packagings are authorized. Each inner receptacle with a removable closure must be packaged so that the closures of the inner containers are upright. The inner receptacles must be securely packed in cushioning material. Strong outer packagings that are able to withstand the rigors of transport must be used. Under 49 CFR 173.150(b), the transport of PreservCyt solution or specimens in a limited quantity is permitted when the weight of the completed outer packaging does not exceed 30 kg (66 pounds). Then, the number of vials is not the limiting factor but the overall package weight is (49 CFR 171.8, 173.24, 172.24a, 173.150(b)(3)).
- **Marking and Labeling**: The proper shipping name (Flammable liquids, n.o.s.) with the technical name (contains methanol) and UN ID number (UN 1993) are not required to be marked on the outer package, provided the outer package is marked with the white square-on-point Limited Quantities Mark, as described in 49 CFR 172.315 and shown in Figure 1. Hazard labels are not required when shipping by highway.



• **Shipping Papers**: No shipping paper required (49 CFR 172.200(b)(3) and 173.150(b)). No emergency response telephone number required (49 CFR 172.604(d)(1)). No placards required.

Commercial Air

New vials of PreservCyt solution or specimens collected in PreservCyt solution may be shipped as a limited quantity as defined in the IATA DGR, Chapter 2, Section 2.7. Chapter 4, Section 4.2, Column G of the IATA Dangerous Goods List, which directs shippers to the proper packing instruction to determine the quantity limits and types of packaging authorized when transporting PreservCyt solution via commercial air:

• **Packaging**: Flammable liquids, n.o.s., PG III identifies the IATA DGR, packing instruction Y344, for limited quantity shipments. The inner receptacle must be securely packed with sufficient cushioning/absorbent material. The outer packaging must pass the drop and stacking tests required under the IATA DGR, Chapter 2, Section 2.7.6. Under Section 2.7.4.2 of the IATA DGR, the transport of PreservCyt solution or specimens is permitted in a limited quantity if the outer packaging weight does not exceed 30 kg (66 pounds). The maximum quantity permitted in one outer packaging is 10,000 mL (10 L). A maximum of 500 of the 20 mL vials

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may be transported in one package as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds).

• Marking and Labeling: Mark the proper shipping name (with technical name), UN ID number, and net quantity of dangerous goods contained in the package on the outer packaging near the receiver's full name and address (IATA Section 7.1.4). The package must also bear the Limited Quantities Mark described in IATA Section 7.1.4.2 and shown in Figure 2. Labeling is required when transporting via commercial air. Affix a "Hazard Class 3 – Flammable Liquids" label to the outer packaging on the same surface as the proper shipping name, near the receiver's full name and address. Package orientation labels are not required (IATA Section 7.2.4.4). Both the shipper's and receiver's full names and addresses must be marked on the outer packaging when shipping via commercial air (IATA 2024).



• **Shipping Papers**: Both a "Shipper's Declaration for Dangerous Goods" and an Air Waybill are required when shipping as a limited quantity. Complete the "Shipper's Declaration for Dangerous Goods" according to the instructions found in IATA DGR, Chapter 8. Complete the Air Waybill per the carrier's instructions.

Note: Federal Express requests the placement of the UN ID number and the proper shipping name in the "Nature and Quantity of Goods" box of the Air Waybill.

WASTE MANAGEMENT.

Refer to DCPH-A Fact Sheet, *Management of Waste from the ThinPrep® Processor*, for waste management issues and procedures specific to the ThinPrep Processor (DCPH-A 2023).

Prepared by: DCPH-A, Environmental Health Sciences Division, Waste Management Program. **Dated:** August 2024