



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

August 08, 2023

1200 New Jersey Avenue, SE
Washington, DC 20590

DOT-SP 21549
(FIRST REVISION)

EXPIRATION DATE: 2025-07-31

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: Repligen Corporation
Waltham, MA
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce aboard aircraft of dangerous goods in apparatus containing a total net quantity of liquid hazardous material exceeding 0.5 L. This special permit provides no relief from the Hazardous Materials Regulations (HMR) or the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
 - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
 - c. No party status will be granted to this special permit.
 - d. This special permit serves as an "exemption" as defined in 1;3.1.1 of the ICAO TI and as a "Competent Authority Approval" as defined under 49 CFR § 107.1.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.222(c)(2)(ii) and Packing Instruction 962 of the ICAO TI in that the total net quantity of a liquid hazardous material may exceed 0.5 L.
5. BASIS: This special permit is based on the application of Repligen Corporation dated April 13, 2023, submitted in accordance with § 107.105 and the public proceeding thereon and additional information dated August 3, 2023.

Tracking Number: 2023084198

6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Dangerous Goods in Apparatus*	9	UN3363	N/A

*Contains UN1824, sodium hydroxide solution, Packing Group II.

7. SAFETY CONTROL MEASURES:

a. PACKAGING: Prescribed packagings are Self-Contained Ultra Filtration Assemblies (SCUFA): 5 m² SCUFA device and a 10 m² SCUFA device containing 596 ml and 1192 ml, respectively of UN1824, sodium hydroxide solution, Packing Group II. Each device is packaged in two 6-mil polyethylene bags, then cushioned top and bottom with polyethylene foam pads. The top of each device is further protected with fiberboard pad. The bagged and padded devices are placed in a fiberboard shipping box. The pad and shipping box for the smaller device is made of 275 lb. Mullen burst test single-wall corrugated fiberboard and the pad and shipping box for the larger device of 275 lb. Mullen burst test double-wall corrugated fiberboard.

b. OPERATIONAL CONTROLS: All requirements in § 173.222 and Packing Instruction 962 of the ICAO TI must be met except that when transported aboard aircraft, the total net quantity of UN1824, sodium hydroxide solution, Packing Group II may exceed 0.5 L but may not exceed 1.192 L.

c. TESTING:

(1) Each SCUFA device must be capable of withstanding without evidence of leakage a pressure differential test equivalent to 95 kPa.

(2) The completed packaging must pass the International Safe Transit Association (ISTA) 3A general simulation test procedure as well as a 1.2 m drop test in accordance with § 178.603 of the HMR.

d. MARKING: Each package, and overpack if used, prepared under the provisions of this special permit must be plainly marked with the special permit number: DOT-SP 21549.

8. SPECIAL PROVISIONS:

- a. Under the terms of this special permit, the grantee may only offer hazardous materials (i.e., the grantee is not authorized as a carrier).
- b. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this special permit, the HMR, and the ICAO TI.
- c. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.
- d. This special permit in no way affects the need to obtain any required authorizations from other agencies of the United States Government or from the competent authorities of the States of origin, transit, over flight, and destination of the consignment, as well as the State of the air operator.
- e. The special permit holder must maintain a record of all activity conducted under the authority granted in this special permit. The record must contain a complete listing and number of shipments made to include and upon request make this information available to a DOT representative or an enforcement official. The record must contain a listing and number of shipments made to include:
 - (1) Dates of shipment; and
 - (2) Description of each type of shipment.

9. MODES OF TRANSPORTATION AUTHORIZED: Passenger-carrying aircraft and cargo-only aircraft.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each aircraft used to transport packages covered by this special permit. The shipper must furnish a copy of this special permit to the air carrier before or at the time the shipment is tendered.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

- o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

Each “Hazmat employee”, as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) —“The Hazardous Materials Safety and Security Reauthorization Act of 2005” (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term “exemption” to “special permit” and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. **REPORTING REQUIREMENTS:** Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for William Schoonover
Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-13, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at <https://www.phmsa.dot.gov/approvals-and-permits/hazmat/special-permits-search>. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: BenMOORE/NICKS