

Pipeline and Hazardous Materials Safety Administration 1200 New Jersey Avenue, SE Washington, DC 20590

# DOT-SP 20975 (FIRST REVISION)

**EXPIRATION DATE: 2026-01-31** 

(FOR RENEWAL, SEE 49 CFR 107.109)

1. <u>GRANTEE</u>: CSL Behring LLC

Bradley, IL

### 2. PURPOSE AND LIMITATION:

- a. This special permit authorizes the transportation in commerce of regulated medical waste in alternative UN approved 11G outer packaging. This special permit provides no relief from the Hazardous Materials Regulations (HMR) 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.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. <u>REGULATIONS FROM WHICH EXEMPTED</u>: 49 CFR §§ 173.197(c)(1) and (e)(1)(i) in that UN 11G fiberboard IBCs and inner bags for solids exceeding 175 L are not authorized.
- 5. <u>BASIS</u>: This special permit is based on the application of CSL Behring LLC dated January 21, 2022 and submitted in accordance with § 107.109.

Tracking Number: 2022014201

## 6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Regulated medical waste, n.o.s. or Clinical waste, unspecified, n.o.s. or (BIO) Medical waste, n.o.s., or Biomedical waste, n.o.s. or Medical waste, n.o.s	6.2	UN3291	II

#### 7. SAFETY CONTROL MEASURES:

#### a. <u>PACKAGING</u>:

#### (1) Inner packaging:

- (i) Polyethylene bag liner filled no more than 3/4 full and sealed with reinforced zip ties. The bag liner must be certified by its manufacturer as having passed the tests prescribed for tear resistance in ASTM D 1922, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method" (IBR, § 171.7 of this subchapter) and for impact resistance in ASTM D 1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method" (IBR, § 171.7 of this subchapter). The film bag must meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.
- (ii) Liquids shall be further packaged in leakproof rigid inner packagings with a capacity no greater than 19 L (5 gallons) conforming to the provisions of Part 173, Subpart B of the HMR.
- (iii) Sharps shall be further packaged in puncture-resistant inner packagings (sharps containers). Each sharps container shall be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer. Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in Part 178, Subpart M, at the Packing Group II performance level. Sharps containers may not be reused.

- (2) Outer Packaging: Two UN 11G fiberboard IBC boxes conforming to Container-Quinn Testing Labs Report Nos. 12899-2, dated May 29, 2019, and 12952-1, dated October 18, 2018. The gross weight of the completed package shall not exceed the net rated weight of the IBC. The IBC is sealed with the use of 2" wide packing tape and secured to a shipping pallet with the use of four (4) half-inch plastic straps with metal crimps to protect against spillage during transport.
- (3) Packages must be certified in accordance with Part 178 Subpart N of the HMR for a UN 11G fiberboard IBC.
- (4) Packages are not authorized for reuse and must be marked "UN 11G FIBERBOARD IBCS ARE NOT AUTHORIZED FOR REUSE".
- b. <u>OPERATIONAL CONTROLS</u>: Packages shall be transported in fully enclosed motor vehicles or trailer.

## 8. <u>SPECIAL PROVISIONS</u>:

- a. 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 and the HMR.
- b. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.
- c. Each fiberboard IBC must be plainly and durably marked "DOT-SP 20975" as specified in §§ 172.302(b) and (c).
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.
- 10. <u>MODAL REQUIREMENTS</u>: A current copy of this special permit must be carried aboard each cargo vessel, aircraft, or motor vehicle used to transport packages covered by this special permit.
- 11. <u>COMPLIANCE</u>: 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. <u>REPORTING REQUIREMENTS</u>: 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.:

Dona By

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.

February 14, 2022

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

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