



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

**March 31, 2022**

1200 New Jersey Avenue, SE  
Washington, DC 20590

DOT-SP 21203  
(FIRST REVISION)

**EXPIRATION DATE:2023-09-30**

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: Daklapack US Inc  
Moonachie, NJ
2. PURPOSE AND LIMITATION:
  - a. This special permit authorizes the manufacture, mark, sale, and use of outer packagings that are not rigid for the transportation in commerce of Category B biological substance samples. 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. In accordance with 49 CFR 107.107(a), party status may not be granted to a manufacturing special permit. These packagings may be used in accordance with 49 CFR 173.22a.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.199(a)(1) in that the outer packaging must be rigid, except as specified herein.
5. BASIS: This special permit is based on the application of Daklapack US Inc dated March 18, 2021 submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR 172.101):

<b>Hazardous Materials Description</b>			
<b>Proper Shipping Name</b>	<b>Hazard Class/ Division</b>	<b>Identification Number</b>	<b>Packing Group</b>
Biological substance, Category B*	6.2	UN3373	N/A

\*Limited to samples.

7. SAFETY CONTROL MEASURES:

a. PACKAGING: Prescribed packaging is a non-specification packaging as described in Belgisch Verpakkingsinstituut bvba Institut Belge De L'Emballage sprl (IBE-BVI) test report number SDR/sdr/G-12.285, dated December 3, 2012 on file with the Office of Hazardous Materials Safety. The packaging consists of a 1.7 ml plastic primary tube placed inside a plastic sleeve, which is placed inside a plastic safety bag with absorbing material capable of containing the full contents of the primary packaging. The plastic safety bag is capable of containing a 95 kPa pressure differential. The safety bag is placed in a plastic envelope as the outer packaging.

b. TESTING: The package must be capable of passing without leakage a drop test as described in § 178.603 from a height of at least 1.2 m and a puncture test as described in § 178.609(h)(1) without leakage from the outer packaging.

c. OPERATIONAL CONTROLS:

(1) MARKING: Each package must be plainly and durably marked "DOT-SP 21203" as required by § 172.301(c).

(2) Each package may be marked with a QR code, which when scanned, provides a direct link to a specific URL where the most recent revision of the special permit can be viewed or downloaded. If the QR code is marked on the packaging, the URL must also be marked on the packaging.

(3) Detailed closure, packing, and shipping instructions must be provided to individuals preparing shipments under the terms of the special permit. Persons offering packages for transportation must comply with the closure, packing, and shipping instructions accompanying the packaging.

8. SPECIAL PROVISIONS:

a. In accordance with the provisions of Paragraph (b) of § 173.22a, persons may use the packaging authorized by this special permit for the transportation of the hazardous materials specified in paragraph 6, only in conformance with the terms of this special permit.

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 and it is reoffered for transportation in conformance with this special permit and the HMR.

c. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation. This requirement does not apply to Category B biological substance samples, offered or transported by a person not considered a “Hazmat employee” (e.g., a consumer offering for transportation or transporting hazardous materials subject to this special permit from the consumer’s private residence).

d. Each packaging manufactured under the authority of this special permit must be either (1) marked with the name of the manufacturer and location (city and state) of the facility at which it is manufactured or (2) marked with a registration symbol designated by the Office of Hazardous Materials Safety for a specific manufacturing facility.

e. A current copy of this special permit must be maintained at each facility where the packaging is manufactured under this special permit. It must be made available to a DOT representative upon request.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle and cargo-only aircraft.10. MODAL REQUIREMENTS:

a. For motor vehicle shipments, a current copy of this special permit must be carried aboard each motor vehicle unless the package is marked in accordance with paragraph 7.c.(2).

b. A current copy of this special permit must be carried aboard each cargo 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. A person not considered a "Hazmat employee" (e.g., a consumer offering for transportation or transporting hazardous materials subject to this special permit from the consumer's private residence) need not receive training on the requirements and conditions of this special permit or the training required by §§ 172.700 through 172.704 but must be provided appropriate instruction to comply with the requirements and conditions of this special permit.

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: BenM/NICKS