

August 07, 2019



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 20922

EXPIRATION DATE: 2020-01-31

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: Burgwedel Biotech GmbH
Burgwedel, Germany

US AGENT: Merck & Co., Inc.
Kenilworth, NJ

2. PURPOSE AND LIMITATIONS:

a. This emergency special permit authorizes the transportation in commerce of Category B Biological Substances by air in quantities exceeding what is authorized in the regulations. This special permit provides no relief from the Hazardous Materials Regulations (HMR) and International Civil Aviation Organization's (ICAO) Technical Instructions (TI) other than as specifically stated herein. The most recent revision supersedes all previous revisions.

b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce. The safety analyses did not consider the hazards and risks associated with consumer use, use as a component of a transport vehicle or other device, or other uses not associated with transportation in commerce.

c. Party status will not 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.

August 07, 2019

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180 and the ICAO TI.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.199(b)(5) and Packing Instruction 650 of the ICAO TI in that the primary packaging contains more than 1 L of material. 49 CFR § 173.199(b)(4) in that neither the primary nor the secondary receptacle is capable of withstanding without leakage an internal pressure differential of at least 95 kPa.
5. BASIS: This special permit is based on the application of Burgwedel Biotech GmbH dated July 24, 2019, submitted in accordance with § 107.117 and the determination that it is necessary to protect life and property.
6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Material Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Biological substance, Category B	6.2	UN3373	N/A

7. SAFETY CONTROL MEASURES:

- a. PACKAGING: As prescribed below and in Burgwedel Biotech GmbH's application dated July 19, 2019.

(1) Primary receptacle: Sartorius Stedim Biotech single-use Flexboy 5 L bag containing no more than 3.5 L of antigen and packed in a UFP Technologies 5 L bioshell.

(2) Secondary packaging: ProAmpac bag that is liquid tight and puncture resistant containing not more than one (1) primary receptacle, and surrounded by sufficient quantity of the cushioning material called "universal absorber fleece" to absorb spills.

(3) Outer packaging: Fefco 0201 fiberboard box containing not more than one (1) secondary packaging.

August 07, 2019

(4) The completed package is further overpacked in an Inmark Biofreeze Dry Ice Pallet shipper. Not more than one (1) outer packaging per overpack is authorized.

(5) No more than 200 kg of dry ice may be contained in a single overpack.

b. OPERATIONAL CONTROLS: PHMSA must be informed, via email (specialpermits@dot.gov), of transport plans at least 36 hours before take-off.

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this special permit, but receives a packaging covered by this special permit, may reoffer it for transportation provided no modification or change is made to the packaging and it is offered 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.

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

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each aircraft or motor vehicle 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.

The Pilot in Command must authorize and affirm, by signature, either in writing or by electronic means, that he/she is aware, and has authorized the subject hazardous material to be aboard the aircraft. The Pilot in Command signed affirmation must be completed before the aircraft pushes back from the gate.

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:

August 07, 2019

- 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

August 07, 2019

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building PHH-30, 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

http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm

Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: Andrew Eckenrode