

July 05, 2018



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 20217
(FIRST REVISION)

EXPIRATION DATE: 2022-05-31

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Nuance Medical, LLC
Carlsbad, CA
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of certain Division 2.1 gases in a DOT 2Q container. 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. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 171.23(b), 171.8, in that the container does not meet the definition of "aerosol" and 173.304a(a)(1) in that the DOT 2Q container is not authorized, except as specified herein.
5. BASIS: This special permit is based on the application of Nuance Medical, LLC dated February 16, 2016, and additional information dated June 5, 2018, submitted in accordance with § 107.109.

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6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Material Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Aerosols, flammable, (each not exceeding 1 L capacity)*	2.1	UN1950	N/A
Liquefied gas, flammable, n.o.s.	2.1	UN3161	N/A

*For importation into the United States and export to Canada, Central and South America only in accordance with paragraphs 8(c) and (d). Not for domestic distribution.

7. SAFETY CONTROL MEASURES:

a. PACKAGING: Prescribed packaging is a DOT Specification 2Q container not exceeding 161 ml (9.82 cubic inch) capacity. The container is not equipped with a pressure relief device. Each container must conform with drawings on file with the Office of Hazardous Materials Approvals and Permits (OHMAP). Each container must be tested as follows: one container out of each lot of 10,000 containers or less, successively produced each day, shall have been pressure tested to determine the burst pressure. The minimum burst pressure must be no less than 23.2 bar (336 psig).

b. OPERATIONAL CONTROLS:

(1) The liquid portion of the gas may not exceed 95% of the container capacity at 130°F.

(2) Each completed container filled for shipment must have been heated until the pressure of the container is equivalent to the equilibrium pressure of the contents at 130°F without evidences of leakage, distortion, or other defect.

(3) The pressure in the container may not exceed 82 psig at 70°F and 177 psig at 130°F.

(4) Each container must be packed in strong outside packagings as described in § 173.301(a) (9).

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(5) Each package may not exceed 30 kg (66 pounds) gross weight.

(6) MARKING: Each outside packaging must be marked "INSIDE CONTAINERS CONFORM WITH DOT-SP 20217".

8. SPECIAL PROVISIONS:

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. Containers may be imported into the United States and transported to Nuance Medical's facility under the international description of "Aerosols, UN1950". The containers must then be relabeled for domestic shipment under the description "Liquefied gas, flammable n.o.s., UN3161".

d. Small quantities, not to exceed 120 containers per shipment, may be exported to Canada, Central and South America for the development of new markets. Containers must be shipped from Nuance's facility under the international description of "Aerosols, UN1950" to the regions named via motor vehicles, cargo vessel and rail freight only. Exportation by air transportation is forbidden.

e. Transportation of Division 2.1 (flammable gases) are not authorized aboard cargo vessel or aircraft unless specifically authorized in the Hazardous Material Table (§ 172.101).

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, and cargo aircraft only (see paragraph 8.e. for additional restrictions).

10. MODAL REQUIREMENTS: 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. The shipper must furnish a copy of this special permit to the air carrier before or at the time the shipment

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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

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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-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: BM/TD