

December 30, 2009



U.S. Department
of Transportation

East Bldg, PHH-30
1200 New Jersey Ave, S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 14488
(FOURTH REVISION)

EXPIRATION DATE: December 30, 2011

1. GRANTEE: Sanofi Pasteur
Swiftwater, PA
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the one-way transportation in commerce of an influenza vaccine in a custom stainless steel batch reactor at a constant pressure of 1-5 psig by use of a cylinder feeding air into the reactor. 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 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. 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 § 173.24(b)(1) in that all valves must be closed to prevent leakage of hazardous material during transportation, except as provided herein; and § 172.301(c) in that the marking requirements are waived.
5. BASIS: This special permit is based on the application of Sanofi Pasteur dated December 10, 2009, submitted in

December 30, 2009

accordance with §§ 107.109 and 107.117 for determination necessary for the protection of life and property.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper shipping name	Hazard Class/ Division	Identification Number	Packing Group
Air, compressed	2.2	UN1002	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging prescribed are two (2) DOT Specification 3AA-2015 cylinders which are shipped as part of a system containing an influenza vaccine. The system consists of a custom ASME Code "U" stamped stainless steel batch reactor with a capacity of 500 liters, DOT Specification 3AA cylinders and associated equipment described in the application for special permit on file with the Office of Hazardous Materials Special Permits and Approvals (OHMSPA).

b. OPERATIONAL CONTROLS -

(1) The pressure in the DOT 3AA cylinders when shipped as part the system containing the influenza vaccine must not exceed 200 psig. The system must be fitted with a regulator capable of stepping down the pressure to 10 psig and fitted with a 40 psig pressure relief valve to prevent over pressuring the reactor vessel containing the vaccine.

(2) The valve on the DOT-specification cylinder containing Air, compressed may be open to maintain a pressure of 1-5 psig within the reactor.

(3) The system containing the influenza vaccine must be transport on a custom reusable stainless steel skid designed a fabricated by WB Moore Inc. as shown on WB Moore Inc. drawing no. 2060823-7 on file with OHMSPA.

December 30, 2009

(4) This special permit authorizes one-way transportation between the Sanofi Pasteur facility in Swiftwater, PA to the Baxter Pharmaceutical Solutions LLC facility in Bloomington, IN or to a facility in Toronto, Canada.

(5) Shipment must be by contract carrier in a dedicated temperature controlled truck capable of maintaining the temperature between 2-8°C. The skid containing the influenza vaccine system will be the only cargo on the motor vehicle. The carrier will utilize two (2) drivers for shipments under this special permit.

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 modifications or changes are 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. The marking requirements of § 172.301(c) are waived.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor Vehicle.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit.

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.

December 30, 2009

- 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 Dr. Magdy El-Sibaie
Acting 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: LAVALLE/CHHOCHMAN/kah/sln