

August 28, 2015



U.S. Department  
of Transportation

East Building, PHH – 30  
1200 New Jersey Avenue, Southeast  
Washington,  
D.C. 20590

**Pipeline and Hazardous  
Materials Safety Administration**

DOT-SP 14429  
(SIXTH REVISION)

|                                         |
|-----------------------------------------|
| <b>EXPIRATION DATE: August 31, 2016</b> |
|-----------------------------------------|

(FOR RENEWAL SEE 49 CFR § 107.109)

1. GRANTEE: Bayer HealthCare, LLC  
(Former Grantee MSD Consumer Care, Inc.)  
Cleveland, TN
2. PURPOSE AND LIMITATION:
  - a. This special permit authorizes the transportation in commerce of a DOT Specification 2P non-refillable aluminum in-side container which has been leakage tested by an automated in-line pressure check in lieu of the hot water bath specified in the Hazardous Materials Regulations (HMR). This special permit provides no relief from the 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. The safety analyses did not consider the hazards and risks associated with consumer use 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 § 173.306(a)(3)(v) in that the use of leakage test other than a hot water bath is not authorized, except as specified herein.

**August 28, 2015**

5. BASIS: This special permit is based on the application of Bayer HealthCare, LLC dated July 21, 2015, submitted in accordance with § 107.105.
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> |
| Consumer Commodity                     | ORM-D                         | None                         | N/A                  |
| Aerosols                               | 2.1                           | UN1950                       | N/A                  |

7. SAFETY CONTROL MEASURES:

- a. PACKAGING - Prescribed packagings are DOT Specification 2P non-refillable inside containers with inner laminate bags containing a Class 3 material (Ethanol solutions). The fill/discharge valve is attached to a laminated bag (PET/ALU/OPA/PP). The bag-on-valve inner package is inserted into the aluminum inside container and affixed with a crimping process. The intermediate space between the two packaging systems is filled with compressed air to a nominal pressure of 100 psig. The packagings conform to the following specifications:
- (1) An inner packaging with a nominal fill capacity of 6 ounces (180 cubic centimeters). The can, laminate bag and mounting cup conform to Schering's drawing numbers PD-0501 and PD-0538 and specifications on file with the Office of Hazardous Material Special Permits and Approvals (OHMSPA).
- (2) An inner packaging with a nominal fill capacity of 7.5 ounces (225 cubic centimeters). The can, laminate bag and mounting cup conform to Schering's drawing numbers PD-0618 and PD-0615 and specifications on file with OHMSPA.

**August 28, 2015**

(3) An inner packaging with a nominal fill capacity of 8 ounces (240 cubic centimeters). The can, laminate bag and mounting cup conform to Schering's drawing numbers PD-0617 and PD-0616 and specifications on file with OHMSPA.

(4) An inner packaging with a nominal fill capacity of 9.5 ounces (285 cubic centimeters). The can, laminate bag and mounting cup conform to Schering's drawing numbers PD-0600 and PD-0601 and specifications on file with OHMSPA.

b. OPERATIONAL CONTROLS -

(1) In lieu of a hot water bath test each completed container must be subjected to an automated in-line pressure check.

(2) If the pressure measured on any container during the in-line pressure check is less than 80 psig or greater than 125 psig then that container must be rejected.

(3) The contents of the inner laminate bag must not exceed 85% of its nominal fill capacity.

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 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 container must be marked "DOT-SP 14429" as specified in § 172.301(c) and shipped in strong outside packagings.

d. Containers filled with a material meeting the definition of a "Consumer commodity" in § 171.8 may be reclassified as ORM-D and shipped as "Consumer commodity" in accordance with § 173.306(i).

**August 28, 2015**

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, cargo aircraft only, and passenger-carrying aircraft.
10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each cargo vessel or 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.

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.

**August 28, 2015**

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 -- OHMSPA, 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  
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, 1200 New Jersey Ave SE, Washington, D.C. 20590.  
Attention: PHH-31.

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](http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm)  
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PO: MOOREBE/SG