

October 29, 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 20284
(SECOND REVISION)

EXPIRATION DATE: 2022-09-30

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: Sharps Compliance, Inc. of Texas
Houston, TX
2. PURPOSE AND LIMITATIONS:
 - a. This special permit authorizes the manufacture, mark, sale and use of non-DOT specification packaging for the transportation in commerce of certain materials authorized to be disposed of under 21 CFR Part 1317, Subpart B. 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. In accordance with 49 CFR 107.107(a) party status may not be granted to a manufacturing 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 Parts 171-180, except as specified herein.

October 29, 2018

5. BASIS: This special permit is based on the application of Sharps Compliance, Inc. of Texas dated October 10, 2018, submitted in accordance with § 107.109.
6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Medicine, liquid, flammable, toxic, n.o.s.*	3	UN3248	II
Medicine, solid, toxic, n.o.s.*	6.1	UN3249	II

*Limited to materials authorized to be disposed of under 21 CFR Part 1317, Subpart B.

7. SAFETY CONTROL MEASURES:

a. PACKAGING: Prescribed single use combination packaging described as "Sharps containment system" for the Medsafe kiosks:

(1) Inner Packaging: The inner packaging is comprised of two liner bags. The first inner liner bag must meet the requirements of 21 CFR 1317.60 and be placed into a second liner bag. The second liner bag must have a minimum thickness of 4 mil and must contain sufficient absorbent to absorb up to 32 ounces of liquid. One of the liner bags must meet the requirements of 49 CFR 173.197(e)(1)(i) and (ii).

(2) Outer Packaging: Strong outer packaging (i.e., fiberboard, plastic, or metal) are authorized. The completed packagings must be capable of meeting the PG II performance level.

(3) The total weight of the packaging plus its contents must not exceed 66 pounds.

(4) Detailed closure, packing and shipping instructions must be provided to individuals preparing shipments under the terms of this special permit. Additionally, individuals preparing shipments under the

October 29, 2018

terms of this special permit must receive training on the requirements and conditions of this special permit.

b. Marking: The marking requirements of 172.301(c) do not apply.

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, but 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 offered 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.

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 Approvals and Permits Division (OHMSAPD) 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.

f. The grantee must notify the OHMSAPD of all locations where authorized packagings are used for collection purposes. Notification must be submitted by e-mail to specialpermits@dot.gov.

October 29, 2018

g. Transportation is authorized only from locations on file with OHMSAPD to the grantee. The grantee is authorized to further offer for transportation or to transport the packages to an authorized disposal facility.

h. This special permit is limited to materials that are collected for the purpose of disposal by registrants authorized by the DEA under 21 CFR 1317.40 or Federal, State, tribal, or local law enforcement when in the course of official duties under 21 CFR 1317.35.

i. This special permit does not provide relief from regulations of other agencies in the United States Government.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle and rail freight.

10. MODAL REQUIREMENTS: None.

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.

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.

October 29, 2018

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 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/TD