



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

January 30, 2024

1200 New Jersey Avenue, SE
Washington, DC 20590

DOT-SP 21707

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: (See individual authorization letter)
2. PURPOSE AND LIMITATIONS:
 - a. This emergency special permit authorizes the transportation in commerce of certain mpox contaminated medical waste for disposal. 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. Unless otherwise stated herein, this special permit consists of the special permit authorization letter issued to the grantee together with this document.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.102(c)(1), Special Provision 131 in that a special permit is issued instead of an approval.
5. BASIS: This emergency special permit is based on the application of Stericycle, Inc. dated January 18, 2024, submitted in accordance with § 107.117 and the determination it is necessary to prevent significant injury to persons.

6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Material Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Medical waste, category A, affecting humans, <i>solid</i>	6.2	UN3549	N/A

7. SAFETY CONTROL MEASURES:a. LIMITATIONS ON SOLID MATERIALS THAT HAVE BEEN CONTAMINATED WITH THE CLADE I MPOX VIRUS:

(1) This special permit authorizes the transportation in commerce of materials that have been contaminated with or are suspected to have been contaminated with the Clade I mpox virus in the packaging system described below.

(2) Inner packagings must be placed into the outer packagings in such a manner as to minimize the risk of damage to the packagings.

b. PACKAGING: The prescribed packagings are as described below for two types of waste.

(1) Packaging for waste contaminated with or suspected of being contaminated with a Category A infectious substance must be packaged according to the method described below unless the grantee documents and notifies the Office of Hazardous Materials Safety (OHMS) that using this packaging method is not possible due to the waste articles being of a larger size than is capable of being placed into a 55-gallon packaging.

(i) Outer Packaging:

(A) A rigid UN Standard or DOT Approved non-bulk packaging with a maximum capacity of 55 gallons. The packaging must be tested and certified at a minimum to the PG II level for solids or liquids. The packaging must be certified to a maximum gross mass greater than or equal to the mass of the packaged waste.

(B) If the outer packaging is fabricated from corrugated fiberboard, it must be a minimum of triple wall corrugated

fiberboard and contain a polyethylene liner with a minimum thickness of 6 mils (0.006 inch). The liner must be sealed and securely closed in accordance with the manufacturer's instructions to prevent the release of any material from the bag if inverted. Fiberboard outer packagings may not be reused under the terms of this special permit.

(ii) Inner Plastic Film Bags: a minimum of two bags are required.

(A) All inner bags must be marked and certified by its manufacturer as having passed:

(1) The tests prescribed for tear resistance in ASTM D 1922, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method". The film bag must meet a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag; and

(2) The tests prescribed for impact resistance in ASTM D 1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method". The film bag must meet an impact resistance of 165 grams.

(B) Each plastic film bag must be sealed and securely closed in accordance with the manufacturer's instructions or, if instructions are not provided, by balloon tying, or with tape, or with zip ties to prevent the release of any material from the bag if inverted. The closure method must not tear, puncture or otherwise damage the bags.

(iii) Sharps waste must be packaged in an FDA-cleared sharps disposal container that is securely closed in accordance with the manufacturer's instructions to prevent leaks and punctures and placed inside the inner bags.

(iv) Optional Outer Salvage Drum: A UN1H2 salvage drum with a maximum capacity of 95 gallons tested and certified as a minimum to the PG II performance level may be used as an additional outer packaging. If used, the drum must be tested and certified to a maximum gross mass greater than or equal to the mass of the filled inner package(s).

(v) After the primary bag is sealed, the exterior surface of the bag must be disinfected with a U.S. Environmental Protection Agency (EPA) registered hospital disinfectant on List Q.

(vi) The primary bag must be placed into a secondary bag and the secondary bag must be sealed. After the second bag is sealed, the exterior surface of the bag must be disinfected with an EPA registered hospital disinfectant on List Q.

(vii) A quantity of absorbent material sufficient to absorb all free liquid (if any) in case of an inner packaging breach must be placed in the bottom of the outer packaging or within the liner of the fiberboard packaging, whichever is applicable.

(viii) The sealed plastic bags are then placed into the outer packaging or outer packaging and liner, if required.

(ix) The sealed outer packaging must be disinfected with an EPA registered hospital disinfectant on List Q.

(x) Optional Packaging: If the optional outer drum is used, the following requirements must be met.

(A) The outer packaging(s) are placed into the UN1H2 salvage drum with a maximum capacity of 95 gallons tested and certified at a minimum to the Packing Group II performance level. After it is filled, the drum must be sealed and securely closed in accordance with the manufacturer's instructions. After closing, the drum must have tape applied to secure the lid and to prevent tampering.

(B) The outer UN1H2 drum must remain closed except when being filled with inner packagings containing the material authorized by this special permit.

(C) The outer 95-gallon drum must not enter into the contaminated area. If it enters the area or is suspected of being contaminated by other means, the exterior of the 95-gallon drum must be disinfected with an EPA registered hospital disinfectant on List Q.

(2) Packaging for larger articles: This packaging system is required for all Clade I mpox contaminated waste that is not capable of being packaged in accordance with paragraph 7.b.(1) above due to the waste articles being of a

larger size than is capable of being placed into a 55-gallon packaging. Clade I mpox contaminated waste shall only be packaged according to this packaging scenario if it can be documented that packaging per paragraph 7.b.(1) above is not possible. OHMS must be notified if this packaging method is to be used.

- (i) The entire surface of the article must be disinfected with an EPA registered hospital disinfectant on List Q.
- (ii) The article must be double bagged in inner bags meeting the requirements of paragraph 7.b.(1)(ii)(A), and the bags must be filled and sealed in accordance with the requirements of paragraphs 7.b.(1)(ii)(B), 7.b.(1)(v), and 7.b.(1)(vi) or the article must be enclosed in two layers of plastic sheet meeting the following requirements:
 - (A) All sheets must be marked and certified by its manufacturer as having passed:
 - (1) The tests prescribed for tear resistance in ASTM D 1922, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method". The film bag must meet a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag; and
 - (2) The tests prescribed for impact resistance in ASTM D 1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method". The film bag must meet an impact resistance of 165 grams.
 - (B) The article shall be sealed inside the first sheet with the openings (ends) twisted closed. All seams shall be sealed with at least two wraps of duct tape. All other openings shall be sealed with at least two wraps of duct tape or 2 zip-ties to ensure closure of the wrap. Disinfect the outer surface of the wrapped article with an EPA registered hospital disinfectant on List Q.
 - (C) The wrapped article must be enclosed in the second sheet with the openings (ends) twisted closed. All seams shall be sealed with at least two wraps of duct tape. All other openings shall be sealed with at least two wraps of duct tape or 2 zip-ties to ensure closure of the wrap. The outer surface of the wrapped article must be disinfected with an EPA registered hospital disinfectant on List Q.

(iii) If practicable, the bagged or wrapped article must be packaged in to a 95-gallon salvage drum in accordance with the requirements of paragraph 7.(b)(1)(x) above; or

(iv) If the item is too large to package in a 95-gallon salvage drum, the wrapped article must be completely enclosed and sealed in a 6 mil polyethylene sheet. All seams must be securely sealed with tape so material cannot escape and disinfect the outer surface of the sheet with an EPA registered hospital disinfectant on List Q. This process must be repeated with the second sheet.

c. OPERATIONAL CONTROLS:

(1) Motor vehicle:

(i) Only vehicles operated by the grantee may be used to transport materials under the terms of this special permit.

(ii) The carrier must meet the criteria for the issuance of a Hazardous Materials Safety Permit (HMSP) pursuant to 49 CFR 385.407(a) and (b) or be specifically reviewed and authorized for transportation by the Federal Motor Carrier Safety Administration.

(iii) Prior to each shipment of materials under the terms of this special permit, the carrier must provide OHMS via email to specialpermits@dot.gov, the following information:

(A) The proposed date and time of pick-up;

(B) The location of each pick-up;

(C) The location of any transloading site (if necessary);

(D) The location of any storage incident to transportation; and

(E) The final destination of the shipment.

(iv) The carrier must also notify OHMS via email to specialpermits@dot.gov when the materials under the terms of this special permit have reached the final destination.

(v) Before loading the package into a transport vehicle, the grantee must ensure that the package is closed and sealed to prevent the release of any material during transportation.

(vi) Loading and unloading the vehicle must be performed using manual means to the maximum extent practicable. Fork trucks or other mechanicals means may not be used for loading or unloading the vehicle unless no other option exists. When fork trucks or other mechanical means are used, extreme care must be taken to prevent puncture and/or rupture of the package. OHMS must be notified prior to use of mechanical means to load or unload the vehicle.

(vii) While in transportation, the doors to the cargo area of the motor vehicle being used to transport the material authorized by this special permit must be closed and locked except when the vehicle is being loaded or unloaded.

(viii) Prior to transportation, the carrier must perform an external visual inspection of the transport vehicle to determine that it is closed and free of leakage.

(ix) The carrier may only transport the vehicle loaded with the material to a destination, for overpacking, treatment or disposal of such materials, without unnecessary delay from the time the carrier's motor vehicle leaves the site of origin. Storage incident to transportation is authorized provided that all of the provisions of the special permit are met and the sealed packages are not opened or repackaged.

(x) The carrier must have a written spill response plan that includes provisions for the decontamination of spilled materials and for personal protective equipment to be carried on the vehicle and used to protect its employees from contact with infectious materials in any form.

(xi) The carrier must respond to any release or suspected release from a package that occurs during transportation. The response must include complete removal of any spilled material and decontamination of the release site, vehicle surfaces and external surfaces of the package involved.

(xii) Each motor vehicle used under the terms of this permit must be decontaminated after each shipment in accordance with applicable federal, state and local laws.

(xiii) The Division Administrator, or designee, for the Federal Motor Carrier Safety Administration's field office within the state of origin must be notified 48 hours in advance, if practicable, of any shipment made under the terms of this permit and each commercial motor vehicle and

driver involved in this operation must be made available for a CVSA Level I hazardous materials inspection prior to transport. A list of these offices can be accessed at the following URL:

<http://www.fmcsa.dot.gov/mission/field-offices>

(xiv) Should any violations of the CVSA North American Standard Out-of-Service Criteria (2014 edition) be discovered during the inspection, the violation(s) must be corrected prior to transporting hazardous materials under this special permit.

(xv) Transportation may only be made to the nearest appropriate disposal facility available at the time the material is offered for transportation. Provided all of the provisions of the special permit are met, multiple shipper locations are authorized for one vehicle. Offloading of the vehicle is only authorized at the final destination, or at a secure facility when transloading is necessary for operational considerations.

(xvi) All contractors preparing mpox wastes for transportation shall comply with the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) and follow the most current precautions prescribed by the United States Centers for Disease Control and Prevention, excluding the recommendation that Category A waste be transported as Category B regulated medical waste and the use of universal precautions. The interim guidance and procedures for the management of patient care articles and medical wastes prescribed by the most updated procedures available on the US CDC mpox webpage shall be implemented for all waste packaging and handling activities to the extent that they comply with the provisions of this special permit:

<https://www.cdc.gov/poxvirus/mpox/index.html>

(2) Cargo vessel:

(i) Transportation via cargo vessel is only authorized when motor vehicle transportation is not practicable.

(ii) Materials are not authorized for shipment on passenger vessels (as defined in § 171.8).

(iii) All materials must be stowed and secured in a freight container or closed cargo transport unit.

(iv) No other material is authorized to be placed in the freight container or closed cargo transport unit, other than infectious material.

(v) A spill response plan/decontamination plan is required (to include personal protective equipment for crew on vessel and apply to tug towing barge as well).

(vi) Notifications must be made to the local Captain of the Port Zones in which the vessel is departing and arriving. The notification (voyage plan) should include identification and quarantine anchorages in case of an incident/vessel contamination. Notification at the departure port should be made as soon as practicable; but, at a minimum it must be 12 hours prior to the intended departure time of the vessel. The port of arrival must be notified prior to departure of the vessel from the loading port.

8. SPECIAL PROVISIONS:

a. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

b. Attendance:

(1) A transport vehicle operating under the terms of this special permit must be attended at all times by its driver or a qualified representative of the motor carrier that operates it unless:

(i) The vehicle is located on the property of the motor carrier, on the property of the shipper or consignee;

(ii) The person in possession of the hazardous materials is aware of the nature of the hazardous materials the vehicle contains and has been instructed in the procedures which must be followed in emergencies; and

(ii) The vehicle is within the person's unobstructed field of view.

(2) For purposes of this special permit:

(i) A transport vehicle is attended when the person in charge of the vehicle is on the vehicle, awake, and not in a sleeper berth, or is within 100 feet of the vehicle and has it within their unobstructed field of view.

- (ii) A qualified representative of a motor carrier is a person who:
 - (A) Has been designated by the carrier to attend the vehicle;
 - (B) Is aware of the nature of the hazardous materials contained in the vehicle they attend;
 - (C) Has been instructed in the procedures they must follow in emergencies; and
 - (D) Is authorized to move the vehicle and has the means and ability to do so.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle and cargo vessel.
- 10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each vehicle used to transport packages covered by this special permit. The carrier shall use hazardous materials routes where designated and practicable.
- 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 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-13, 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 <https://www.phmsa.dot.gov/approvals-and-permits/hazmat/special-permits-search>. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: RR/TG