

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Receive Soil
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system.

PERMITTEE NAME: Tammy Greer COMPANY: Microbial ID, Inc. ADDRESS: 125 Sandy Drive Newark, DE 19713 MAILING ADDRESS: 125 Sandy Drive Newark, DE 19713 PHONE: (302) 737-4297 ALT. PHONE: EMAIL: tgreer@midilabs.com FAX:	PERMIT NUMBER: P330-18-00331 APPLICATION NUMBER: P525-210301-001 DATE ISSUED: 11/07/2018 DATE AMENDED: 03/04/2021 EXPIRES: 11/07/2021 HAND CARRY: No FACILITY NUMBER: 6290 FACILITY ACCOUNT: Microbial ID, Inc. RESEARCH CENTER: FACILITY NAME: FACILITY ADDRESS: 125 Sandy Drive Newark, Delaware 19713 FACILITY GPS: MAIL ADDRESS: 125 Sandy Drive Newark, Delaware 19713 FACILITY CONTACT: PHONE: 302-737-4297 ext. 115 ALT. PHONE: FAX: EMAIL: tgreer@midilabs.com
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PORTS OF ARRIVAL/PLANT INSPECTION STATIONS: AK, Anchorage; AL, Huntsville; AL, Mobile; AZ, Douglas; AZ, Lukeville; AZ, Naco; AZ, Nogales; AZ, Phoenix; AZ, San Luis; AZ, Tucson; CA, Calexico; CA, El Segundo; CA, Fresno; CA, Long Beach; CA, Oakland; CA, Ontario; CA, Otay Mesa; CA, Port Hueneme; CA, Sacramento; CA, San Diego; CA, San Jose; CA, San Ysidro; CA, South San Francisco; CA, Tecate; CO, Denver; CT, Hartford; CT, New Haven; DE, Dover; DE, Wilmington; FL, Ft. Lauderdale; FL, Ft. Myers; FL, Ft. Pierce; FL, Jacksonville; FL, Key West; FL, Miami; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc.); FL, Orlando; FL, Pensacola; FL, Port Canaveral; FL, Port Everglades; FL, Sanford; FL, Tampa; FL, West Palm Beach; GA, Atlanta; GA, Savannah; GU, Agana; HI, Hilo; HI, Honolulu; HI, Kahului; HI, Kailua-Kona; HI, Lihue; ID, Eastport; IL, Chicago; IN, Indianapolis; KY, Louisville; MA, South Boston; MD, Baltimore; MD, Laurel; ME, Bangor; ME, Calais; ME, Houlton; ME, Portland; MI, Detroit; MI, Port Huron; MI, Romulus; MI, Sault Saint Marie; MN, Duluth; MN, Grand Portage; MN, International Falls; MN, Minneapolis; MO, Kansas City; MO, St. Louis; MP, Commonwealth of the Northern Mariana Islands; MS, Gulfport; MS, Port Bienville; MT, Raymond; MT, Roosville; MT, Sweetgrass; NC, Raleigh; NC, Wilmington; ND, Dunseith; ND, Pembina; ND, Portal; NJ, Linden; NM, Albuquerque; NM, Columbus; NM, SantaTeresa; NV, Las Vegas; NY, Albany; NY, Alexandria Bay; NY, Brooklyn; NY, Buffalo; NY, Champlain, Rouses Point; NY, Jamaica; NY, Newburgh; OH, Ashtabula; OH, Cincinnati; OH, Cleveland; OH, Columbus; OH, Toledo; OH, Wilmington; OK, Oklahoma City; OR, Portland; PA, Allentown; PA, Harrisburg; PA, Philadelphia; PA, Pittsburgh; PA, Scranton; PR, Aguadilla; PR, Carolina; PR,

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Fajardo; PR, Mayaguez; PR, Ponce; RI, Warwick/Providence; SC, Charleston; TN, Memphis; TN, Nashville; TX, Austin; TX, Brownsville; TX, Corpus Christi; TX, Dallas; TX, Del Rio; TX, Eagle Pass; TX, El Paso; TX, Fabens; TX, Falcon; TX, Fort Hancock; TX, Freeport; TX, Galveston; TX, Hidalgo; TX, Humble; TX, Laredo; TX, Los Indios; TX, Pharr; TX, Port Arthur; TX, Presidio; TX, Progreso; TX, Rio Grande City; TX, Roma; TX, San Antonio; TX, Victoria; UT, Salt Lake City; VA, Dulles; VA, Norfolk; VI, St. Croix; VI, St. Thomas; VT, Berlin; WA, Blaine; WA, Oroville; WA, Port Angeles; WA, SeaTac; WA, Sumas; WI, Green Bay; WI, Milwaukee

Under the conditions specified, this permit authorizes the following:
Quantity of Soil per Shipment and Treatment
 Sterilization will interfere with intended use - Your facility **MUST** be inspected and approved to receive this soil

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

INSTRUCTIONS TO DHS CBP INSPECTORS FOR IMPORTED SOIL SHIPMENTS ROUTED TO RECEIVING FACILITY:
 For hand carry of soil, an official of CBP Agricultural Programs and Trade Liaison (APTL) would have been notified to document and facilitate the entry of the soil (See hand carry conditions below if stipulated).

Otherwise:

- 1) Confirm that the shipment under this USDA PPQ P330 permit is under bond to the point of entry.
- 2) Validate the permit in ePermits using the CBP search feature.
- 3) Confirm that the imported shipment has a valid USDA PPQ Form 550 Black/White label.
- 4) For questions or concerns, contact the USDA-APHIS-PPQ Permit Unit in Riverdale, MD, at 866-524-5421 and ask to speak with a compliance officer.

PERMIT GUIDANCE

- 1) Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury; please refer to <https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>
- 2) This permit does not authorize importation, interstate movement, possession, and/or use of strains of genetically engineered regulated materials/organisms (created by the use of recombinant DNA technology).
- 3) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.shtml
- 4) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 5) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 6) If you are considering renewal of this permit, an application should be submitted at least 90 days prior

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to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

CHEMICAL/PHYSICAL ANALYSIS IMPORTATION

USDA-APHIS issues this permit to Tammy Greer with Microbial ID, Inc. in Newark, Delaware. The permit authorizes the importation of soil from all foreign sources (except countries with sanctions or embargoes by U.S. State Department) only for chemical/physical analysis in a controlled laboratory environment at the named facility on the permit.

1. This permit is issued by the United States Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.

- A copy of the permit or the permit number must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- The regulated material and shipping container(s) are subject to inspection by officials of U.S. Customs and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for any associated expenses.
- If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The Permit holder must comply with all the items listed below. In cases where notification is required, the notification must be made to the PPQ Pest Permit Staff at 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification. You must also notify the PPQ State Plant Health Director (SPHD) in your State. Access the list of SPHDs at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/ct_sphd.

- maintain a valid PPQ 330 permit as long as any portion of the regulated soil has not been treated or disposed of in accordance with these permit conditions,
- maintain an official permanent work assignment or affiliation at the address on this permit,
- notify PPQ of any change in the permit holder's work assignment, place of business, or affiliation,
- not assign or transfer this permit to other persons without prior PPQ authorization,
- notify PPQ of the receipt of an unauthorized and/or misdirected shipment of regulated soil and hold it until further instruction from PPQ,

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- notify PPQ if the shipment includes any unusual/unexpected contents (including live insects and snails) and take all prudent measures to contain them until further instruction from PPQ,
- notify PPQ of any unauthorized or accidental release of the regulated soil and adequately mitigate the resulting environmental impacts,
- notify PPQ if the facility or equipment is damaged, destroyed, or otherwise compromised,
- notify PPQ if you intend to let your permit expire and you will no longer receive, handle, and/or dispose of regulated soil.

3. Prohibitions/Limitations:

Regulated soil must not be used:

- in field research or for other release into the environment before sterilization,
- for isolating, culturing, extracting, or concentrating live organisms,
- as a growing medium, unless specifically authorized in this permit.

4. Shipping/Movement

1) All shipments must consist of at least two inner packages and an outer shipping container securely sealed so that all prevent unauthorized loss of the regulated soil. The innermost packages (e.g. polythene super sacks, sealed drums, yard plastic-lined boxes, etc.) must be sealed and adequate to withstand pressure, temperature, and other climatic conditions incidental to shipment. The outer container must be rigid and durable enough to remain sealed and structurally intact to endure typical shipping conditions (dropping, stacking, impact from other freight, etc.). The conveyance must be secured by a lock, seal, or similar device. The permit holder is responsible for communicating these requirements to the shipper.

2) For soil that originates in Hawaii and Puerto Rico, a copy of this permit or permit number and the shipment must be presented to APHIS-Plant Protection and Quarantine (PPQ) for inspection and clearance prior to departure. For soil that originates in the U.S. Virgin Islands, a copy of this permit or the permit number and the shipment must be presented to APHIS-PPQ in Puerto Rico for inspection and clearance prior to arrival in mainland U.S. For more information on how to ship your package to APHIS-PPQ in Puerto Rico, visit our website at:

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/plant-pests/sa_soil/soil-shipping-requirements.

Following inspection, soil shipments from Hawaii, Puerto Rico, and the U.S. Virgin Islands are authorized to enter at any arrival point on the mainland U.S.

3) Unless the regulated soil is hand carried by an individual specifically authorized in this permit, it must be shipped by bonded carrier to the port of entry. Following release by CBP, further movement to the APHIS-PPQ approved facility must occur by means of a generally recognized commercial carrier.

4) The shipment must be free from foreign matter or debris, plants and plant parts, and other macro-organisms, such as insects, cyst nematodes, mollusks and acari. Regulated material commingled with unauthorized material will be treated, seized, re-exported, or destroyed (in part or whole).

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5) All solid wood packing material (SWPM) accompanying the shipment must be in compliance with ISPM 15 treatment regulations and IPPC stamp requirements and enforcement. Noncompliant shipments will be treated, re-exported or destroyed at the consignee's expense.

6) Further distribution or movement of the regulated soil is not allowed without prior approval from the APHIS-PPQ SPHD in your State. Access the list of SPHDs at <https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/sphd>. For such movements, you must follow the packaging standards described in these permit conditions, except that the use of black and white labels is not required.

7) Certain domestic mainland soil is regulated separately under 7 CFR 301. This permit does NOT authorize the movement of such soil. For further information on the movement of domestic mainland soil visit: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-orga-nism-and-soil-permits/sa_soil/ct_domestic_soil.

5. Shipping Labels/Labeling

After issuance of this P330 permit and prior to importation, you will need to request PPQ Form 550 Black/White shipping label(s) at least 5 business days in advance of shipping date. If you applied online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to BlackWhiteGreenYellowlabelrequest@usda.gov. Specify the permit number and the total number of labels needed. All email requests must come from the permit holder or appointee and if requested by the appointee, they must Cc the permit holder on all requests. You may request additional labels the same way. We will send you the labels by email as a pdf.

A label must be attached with clear tape to the exterior of each package being imported under this permit. (It is NOT necessary to provide a shipping label for every sample contained within one package e.g. 5 bottles/bags/vials within one box needs only ONE label, not five). The labels have detailed instructions for use on the reverse side. You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit. Failure to do so may result in refused entry or destruction of your package.

Enclose the following supplemental information in each shipment:

- Permittee Name
- Permit number
- Label number

Underlying packaging/wrapping must carry the address, billing, and any other information required to direct the shipment to its final destination (i.e., the permit holder's address; N.B., USDA APHIS does not defray any additional shipping costs incurred for transiting the shipment through an inspection station as the initial US destination).

NOTE: the PPQ Form 550 Black/White label is NOT required on shipments of soil that originate in

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Hawaii, Puerto Rico, and the U.S. Virgin Islands.

6. Facility (Storage/Handling)

1) All regulated soil must be safeguarded at all times during movement, handling, and storage, until sterilized by one of the treatment method(s) specified in this permit. Upon arrival at the APHIS-PPQ approved facility, the regulated soil must be stored in two levels of secured containment until transferred or sterilized. As long as regulated soil is present, the containment and all other affected areas of the facility must be restricted to access by authorized personnel only.

2) All containers and storage areas will be labeled: “Regulated Soil – Sterilize before Disposal” (or an acceptable equivalent). The secured containment area must store only regulated material or, if the area also houses unregulated material, the regulated material must be clearly segregated from the unregulated material as well as being appropriately labeled.

3) The permit holder is responsible for the activities of those individuals working with the regulated soil. Everyone handling the regulated soil must read, agree to, and initial the permit conditions before working with or handling the regulated material. These initialed conditions do not need to be submitted to APHIS-PPQ but must be readily accessible in the event of an inspection and presented upon request.

4) Modifications to the facility or any procedural changes that affect the handling of the regulated soil must be approved by APHIS-PPQ prior to making changes. Please contact the PPQ Pest Permit Staff (email: pest.permits@usda.gov; phone: 866-524-5421; address: 4700 River Road, Unit 133, Riverdale, MD 20737; fax: 301-734-8700).

7. 1) Treatment/Disposal

All decontamination, sterilization, and disposal must comply with one of the methods authorized by the permit conditions. Prior to disposal, all regulated soil must be sterilized by one of the following methods:

Autoclave

- a. Autoclave at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Place autoclave tape or other indicators on each load prior to treatment. Check the autoclave tape or other indicator on each container to verify color change before disposal.
- c. Calibrate annually according to the manufacturer’s instructions and maintain written records.
- d. Use a commercially available biological indicator kit every 3 months, containing bacterial spores (e.g. *Geobacillus stearothermophilus* species) that are rendered unviable at 121 Celsius (250 Fahrenheit). Follow the manufacturer’s instructions. Service and retest the autoclave if any growth is observed.

Dry Heat

Use one of the following minimum temperature ranges and minimum exposure time combinations:
110 – 120.5 Celsius (230 – 249 Fahrenheit) for 16 hours

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- 121 – 154 Celsius (250 – 309 Fahrenheit) for 2 hours
- 154.4 – 192.5 Celsius (310 – 379 Fahrenheit) for 30 minutes
- 193 – 220 Celsius (380 – 429 Fahrenheit) for 4 minutes
- 221 – 232 Celsius (430 – 450 Fahrenheit) for 2 minutes

NOTE: Time starts when the entire sample reaches the required temperature and you must utilize a suitable temperature probe or currently calibrated thermometer for verification. The soil must be spread evenly throughout the chamber and not exceed 6 inches in depth.

Hydroclave

- a. Hydroclave at a minimum of 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes, or at a minimum of 132 Celsius (267 Fahrenheit) for a minimum of 15 minutes.
- b. Observe the temperature sensor to ensure that the hydroclave maintains its required temperature.
- c. Calibrate the hydroclave annually according to the manufacturer’s instructions and maintain written records.

Incineration

With the exception of metal and glass containers, all regulated and associated material must be reduced completely to ash at the end of the incineration cycle.

As an alternative to the sterilization requirements listed above, disposal of regulated soil and any material contaminated with regulated soil may be conducted off site by a Disposal Facility holding a current PPQ Permit for Bulk Disposal or a Compliance Agreement for Bulk Disposal. Vendor may or may not be in the same state. SPHD approval is required prior to any movement of the regulated soil and approval is required in both the sending state and receiving state. Access the list of SPHDs at https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/ct_sphd. All regulated soil and any material contaminated with regulated soil must be double contained during transport to the Disposal Facility to prevent any unauthorized dissemination of the regulated soil. For records maintenance requirements, refer to the record keeping permit condition.

No other sterilization methods are allowed without prior review and approval from PPQ Pest Permit Unit Staff. .

8. Decontamination of surfaces, tools, equipment, supplies and related materials

- 1) Unless other disposal arrangements have been approved in advance by PPQ Pest Permit Staff, all items coming in direct contact with, or exposed to, the regulated soil -- including but not limited to glassware, countertops, equipment, waste material, effluent, and shipping materials -- must be sterilized/sanitized/decontaminated prior to re-use or removal from the APHIS-PPQ approved facility, and prior to the expiration of this permit.

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- 2) Use any of the following, either alone or in combination:
- a) immersed in minimum of .525 percent sodium hypochlorite (household bleach from the bottle is a minimum of 5 percent) for at least 20 minutes
 - b) immersed in 70 percent alcohol or ethanol for at least 30 minutes,
 - c) treated with quaternary ammonium compounds per manufacturer's specifications,
 - d) using one of the soil sterilization methods above.

3) Hydroclave or autoclave effluent as stipulated above.

9. Training requirements/Records/Record-Keeping

1) Standard Operating Procedures (SOPs) must be filed with, and approved by, the PPQ Pest Permit Staff at: email: pest.permits@usda.gov; phone: 866-524-5421; fax: 301-734-8700; address: River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, the permit conditions take precedence. APHIS-PPQ must approve any changes to the SOPs before implementation. At a minimum, the SOP should describe how you will maintain compliance with APHIS-PPQ regulations. It must include how you plan to: transport, handle/process, store, safeguard, treat, and dispose of the regulated soil, effluent, and anything else coming into contact with the regulated soil. The SOP must also contain instructions regarding the cleanup of potential spillage of regulated soil and must be posted in areas where soil is stored and processed. A current copy of the SOP must be available at the time of facility inspection.

2) All employees working with the regulated soil must complete annual training. The training must cover the requirements on this permit and the Standard Operating Procedures submitted to APHIS-PPQ. Both a copy of the permit and the SOPs must be available at all times for the facility staff to consult.

Training records on each employee must be maintained for a period of three (3) years from the date the record was created and a list of all persons working with the soil in the APHIS-PPQ approved facility must be maintained.

3) The permit holder must keep records of all shipments received and samples processed under this permit. These records must be retained for a period of three (3) years after disposal of the soil, or (3) years after its transfer to another APHIS-PPQ approved facility. If soil is transferred between approved facilities, its identity must be maintained for traceability.

The records must include:

- a. Date of arrival of each shipment.
- b. Origin of the regulated soil.
- c. Total weight of regulated soil in each shipment.
- d. Date and weight of disposed or transferred amounts of regulated soil.
- e. Method of disposal or location where the regulated soil was transferred to.

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4) All records retained under this permit must be made available to Federal and State regulators upon request.

END OF PERMIT CONDITIONS

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