



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
CITY VIEW PLAZA II BUILDING, 7TH FLOOR
ROUTE 165 GUAYNABO, PUERTO RICO 00968

August 8, 2023

SENT VIA EMAIL:

Pall Life Sciences Puerto Rico LLC
STATE ROAD 194 KM. 0.4
FAJARDO, 00738
C/O: Ms. Jalixa Díaz
Emails: jalixa_diaz@pall.com; natalia_perez@pall.com

RE: RCRA § 3008 – NOTICE OF VIOLATION
Pall Life Sciences Puerto Rico LLC
EPA ID: PRD981139611
CEPD-RCRA-23-0000-3008-006

Dear Ms. Jalixa Díaz:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 et seq. Pursuant to RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste as set forth in 40 Code of Federal Regulations (C.F.R.) Parts 260-272. For the purposes of this Notice of Violation (NOV), the hazardous waste regulations governing the generation of hazardous waste were promulgated in 1980 and amended by HSWA in 1984. The Commonwealth of Puerto Rico is not authorized by the EPA to conduct a hazardous waste program and to enforce RCRA under Section 3006 of RCRA, 42 U.S.C. § 6926.

On or about March 16, 2023, a duly authorized representative of the EPA conducted a Compliance Evaluation Inspection (CEI) of the Pall Life Sciences Puerto Rico LLC., located in Fajardo, Puerto Rico, (the “Facility”) pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA representative found the Facility in violation of §§ 40 CFR § 262.17(a)(1)(ii), 40 CFR 262.17(a)(1)(vii)(C), 40 CFR § 262.17(a)(5)(i)(A), 40 CFR § 262.17(a)(5)(i)(B), and 40 CFR 262.262(b) of the RCRA Regulations.

This Notice of Violation (Enclosure I) is issued pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by RCRA and HSWA, 42 U.S.C. §§ 6901 and 6928. Issuance of this NOV and compliance with its terms does not preclude EPA from taking formal enforcement action against you and/or your company, including a monetary penalty, under Section 3008 of RCRA, 42 U.S.C. § 6928, or any other applicable regulation or statute.

If you have not already done so, you must take immediate action to correct the violations described in Enclosure I. Please submit, within thirty (30) days of the receipt of this letter, a response which includes (1) a description of the actions you have taken to correct the violation noted in Enclosure I, (2) documentation that the violation has been corrected, and (3) a description of the procedures that will be put into place to prevent such violation from occurring in the future. For consistency, please provide your answers in a format which is keyed to the sections as outlined in Enclosure I to this letter.


Your response to this NOV can be send through email to the following email address caballer.rosana@epa.gov and can also be mailed to the following address:

Rosana Caballer-Cruz, Enforcement Officer
Response and Remediation Branch
U.S. Environmental Protection Agency - Region 2
Caribbean Environmental Protection Division
City View Plaza II, suite 7000
#48 PR-165 km 1.2
Guaynabo, PR 00968-8069

Failure to respond in full to the above requirements may result in federal enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. If you have any questions regarding this matter, please contact Ms. Rosana Caballer-Cruz, from my staff, at 787-977-5880 or via e-mail at caballer.rosana@epa.gov.

Sincerely,
**CARMEN
GUERRERO
PEREZ**

Carmen R. Guerrero Pérez
Director

 Digitally signed by
CARMEN GUERRERO PEREZ
Date: 2023.08.08 13:56:14
-04'00'

Enclosures: Enclosure I - Notice of Violation

cc: Ms. Lorna Rodríguez, RCRA Enforcement Section Chief
Puerto Rico Dept. Natural & Environmental Resources



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ENCLOSURE I – RCRA § 3008 NOTICE OF VIOLATION

Pall Life Sciences Puerto Rico LLC
EPA ID: PRD981139611
CEPD-RCRA-23-0000-3008-006

On or about March 16, 2023, a duly authorized representative of EPA conducted a Resource Conservation and Recovery Act (RCRA) Hazardous Waste Compliance Evaluation Inspection (CEI) of the PALL LIFE SCIENCES PUERTO RICO, LLC. (PALL) located at STATE ROAD 194 KM. 0.4 FAJARDO, PUERTO RICO, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA has identified the following violations of the RCRA regulations.

i. 40 C.F.R. § 262.17(a)(1)(ii)

At the time of the inspection, PALL failed § 262.17(a)(1)(ii) which required *“if a container holding hazardous waste is not in good condition, or if it begins to leak, the large quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of this section...”*

The facility failed to comply with this requirement in the 90-day HWAA. Here, one (1) 55-gallon white plastic container with isopropyl alcohol was observed with a dent.

ii. 40 C.F.R. § 262.17(a)(1)(vii)(C)

At the time of the inspection, PALL failed § 262.17(a)(1)(vii)(C) which required *“a container holding a hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.”*

The facility failed to comply with this requirement in the 90-day HWAA. Here, one 55-gallon white plastic container with diluted NaOH, labeled as hazardous waste, was observed with a corrosive pictographic label. This container was not separated from the other flammable materials observed at the facility’s 90-day HWAA or was not protected from them by means of a dike, berm, wall, or other device.

iii. 40 C.F.R. § 262.17(a)(5)(i)(A)

At the time of the inspection, PALL failed § 262.17(a)(5)(i)(A) which required “*A large quantity generator must mark or label its containers with the following: (A) The words “Hazardous Waste...”*”.

The facility failed to comply with this requirement in the Syringe Area. Here, one (1) 20-gallon white plastic container was observed without a hazardous waste label.

iv. 40 C.F.R. § 262.17(a)(5)(i)(B)

At the time of the inspection, PALL failed § 262.17(a)(5)(i)(B) which required “*an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704)*...”

The facility failed to comply with this requirement in the Manufacturing Area and the Syringe Area. At the Manufacturing Area, one (1) 10-gallon red metal container with tinta/paños/guantes was observed without a pictographic label and/or indication of the hazard while at the Syringe Area, a 10-gallon yellow plastic container with napkins and filters, and a 5-gallon red plastic container with napkins with alcohol and ink were observed without a pictographic label and/or indication of the hazard.

v. 40 C.F.R. § 262.262(b)

At the time of the inspection, PALL failed § 262.262(b) which required “*A large quantity generator that first becomes subject to these provisions after May 30, 2017 or a large quantity generator that is otherwise amending its contingency plan must at that time submit a quick reference guide of the contingency plan to the local emergency responders identified at paragraph (a) of this section or, as appropriate, the Local Emergency Planning Committee...*”

The facility failed to comply with this requirement. During the review of the facility’s Contingency Plan at the time of the inspection, it was observed that the document did not have the quick reference guide. Although the facility provided, via email at a later date, the quick reference guide, according to the information gathered, this quick reference guide appears to have been generated after amending its Contingency Plan as a result of the inspection. According to records evaluated during the inspection, the

facility's Contingency Plan, aka ICP, was dated September 2022. The quick reference guide provided for review after the inspection was dated March 2023.