



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

## 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.