

**Resource Conservation and Recovery Act (RCRA) Corrective Action
Determination of Remedy Construction
RCRAInfo Code CA550**

Facility Name: Fenwal International Inc.
Facility Address: ROAD 357 KM 0.8, MARICAO, PR 00606
Facility EPA ID#: PRD000706473

Facility Information

Fenwal International Inc. (hereinafter Fenwal) operates a medical devices manufacturing facility at two (2) properties owned by the Puerto Rico Industrial Development Company (PRIDCO), located at State Road PR-357, Km. 0.8, in the Municipality of Maricao, Puerto Rico (the Facility). The total surface area of the properties adds up to approximately 15.2 acres. The Facility includes two (2) main buildings with a total of approximately 100,000 square foot used for office, manufacturing, and related operations. The Facility was operated by Travenol Laboratories, Inc., until July 22, 1987, when the operator became Baxter Healthcare Corp. of Puerto Rico. In the year 2007, TPG, a group of investors, bought the Fenwal Division from Baxter Healthcare Corporation and in 2012, Fresenius Kabi bought Fenwal International from TPG (Ref. 1). Manufacturing operations at the facility began in May 1972 and continue to this date (Ref.1, 2)

Back on 1980, the facility submitted to EPA the Part A Permit application and obtained Interim Status as a Treatment, Storage, and Disposal Facility (TSDF), under the Resource Conservation and Recovery Act (RCRA) Program (Ref. 2). According to RCRAInfo, the two (2) units under interim status were finally clean-closed in September 1986. Since 1996, the facility appears as a Small Quantity Generator (SQG). Currently, the facility still maintains their SQG classification (RCRAInfo).

Summary of Solid Waste Management Units (SWMUs) and Areas of Concern (AOCs):

In 1988, the former Puerto Rico Environmental Quality Board (PREQB) conducted a RCRA Facility Assessment (RFA) and identified two (2) Solid Waste Management Units (SWMUs) and five (5) Areas of Concern (AOCs).

SWMU's:

SWMU-1	Hazardous Waste Containers Storage Area
SWMU-2	Neutralization Tank

AOC's:

AOC-1	Raw Material Storage Area
AOC-2	Flammable and Raw Material Storage Area
AOC-3	Chemical Laboratory
AOC-4	Underground Storage Tanks
AOC-5	Boiler Room

The 1988 RFA recommended a sampling visit only for AOC-2 referred to as a "Flammable and Raw Material Storage Area", located in the backyard of the north side of plant #2.

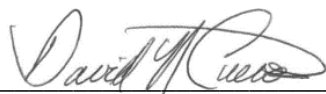
AOC-2 consisted of a steel building within a key-fenced area with a concrete floor with dimensions of 31' L X 20' W and surrounded by a curb 8" height X 6" wide, as described in the 1988 RFA. The physical description of AOC-2 has remained the same up to present day without any physical alteration. The description of AOC-2 contained in the 1988 RFA indicated that this area was used as a raw material storage area for Cyclohexanone, Methyl Ethyl Ketone, Isopropyl Alcohol, Chlorine and Dimethyl Chloride. AOC-2 was never used to store hazardous wastes. The AOC-2 is no longer used for the storage of flammable and the raw materials, but rather used for the storage of wooden pallets, PVC pipes, acrylic material, and galvanized tubes, which materials are to be used elsewhere in the Facility. At some point in time paper for recycling had also been stored inside AOC-2. The 1988 RFA indicted that during the visual site investigation some stains on the soil located beneath the drainage of AOC-2 were observed and recommended that further investigation of this area be conducted through sampling and analysis activities (Ref. 1, 2).

On December 2016, EPA issued a letter to Fenwal imposing a RCRA Facility Investigation (RFI), after finding that the recommendations made in the 1988 RFA regarding AOC-2 had not been addressed (Ref 3). After approval of the Work Plan by EPA on October 2019 (Ref. 4, 5), Fenwal conducted the RFI on June 2020 to determine presence, if any, of volatile organic compounds (VOCs), semivolatile organic compounds (SVOCs) and non-halogenated organics in soil sampled from AOC-2 (Ref. 1). Results of the RFI show that no constituents of concern occur in soil media above applicable screening levels, for industrial soil, in the vicinity of AOC-2 (Ref. 1).

Determination of Remedy Construction (CA550NR) granted

Based on a review of the information referenced in this document, a determination about "Remedy Construction" has been granted, where no construction is necessary (CA550NR). On June 2020, Fenwal conducted soil sampling as part of the RCRA Facility Investigation. Surface (0-2 ft) and subsurface (2-10 ft) soil samples were collected from borings adjacent to the to the four sides of the dike at AOC-2 and analyzed for VOCs, SVOCs and non-halogenated compounds. Results indicate soils adjacent to AOC-2 do not have constituents of concern above applicable screening levels for industrial soil. (Ref. 1). Given the results of the RFI, no groundwater contamination is expected and No Further Action (NFA) is necessary at the facility. On September 3, 2020, EPA concurred with Fenwal regarding the NFA determination for the facility (Ref. 6). This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

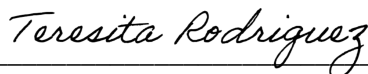
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Date: September 8, 2020

Approved by:



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Date: Sept. 22, 2020

References:

1. Resource Conservation and Recovery Act Facility Investigation (RFI) Final Report, FENWAL International, Inc., Maricao, Puerto Rico. Prepared by UNIPRO Architects and Planners, LLP. August 2020.
2. RCRA Facility Assessment Report, Baxter Healthcare Corp. of Puerto Rico, Maricao, Puerto Rico, PRD000706473. Prepared by Puerto Rico Environmental Quality Board. August 1988.
3. Correspondence from Carmen R. Guerrero-Pérez, USEPA, to Ms. Joann Molina, Fenwal, Re: *Request of RCRA Facility Investigation*, Fenwal Kabi, Maricao, Puerto Rico. December 6, 2016
4. RCRA Facility Investigation Work Plan, Fenwal International Inc., Maricao, PR. September 16, 2019.
5. Correspondence from Carmen R. Guerrero-Pérez, USEPA, to Ms. Joann Molina, Fenwal, Re: *Approval of the September 2019 RCRA Facility Investigation Work Plan*, Fenwal International Inc., Maricao, PR. October 10, 2019.
6. Correspondence from Carmen R. Guerrero-Pérez, USEPA, to Ms. Joann Molina, Fenwal, *Approval of the August 2020 Final RCRA Facility Investigation Report*, Fenwal International, Inc., Maricao, Puerto Rico. September 3, 2020.

Locations where references may be found:

References reviewed to prepare this EI determination have been identified under the Facility Information Section. Reference materials are available at U.S. EPA, Region 2.

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