

Resource Conservation and Recovery Act (RCRA)

Compliance Evaluation Inspection

Facility Name:	Auro PR Inc – Caguas		
EPA ID Number:	PRD987369766		
Date of Inspection:	August 30, 2023		
Generator Status in Record:	Large Quantity Generator (LQG)		
Generator Status at the time of inspection:	LQG		
RCRA Permitted:	No		
Basis for Inspection:	Core Program		
Corrective Action:	No		
Potential EJ Concern	Yes. At least 1 EJ Index is above the 80% USA Percentile. (See Appendix C)		
Potential Flood Prone Area	Yes. The Facility's boundary is located within the 100-Year FEMA Flood Zone. (See Appendix D)		
Facility Physical Location: (Municipality, PR, zip code)	Caguas West Industrial Park Lot 24B PR-156 KM 58.8 Caguas, PR 00725		
Geographical Coordinates:	18.233730, -66.050820		
Facility Owner:	Aurobindo PR LLC	787-704-7500	
	Lot 24B PR-156 KM 58.8 Caguas, PR 00725		
Facility Operator:	Aurobindo PR LLC	787-704-7500	
	Lot 24B PR-156 KM 58.8 Caguas, PR 00725		
NAICS:	325412; Pharmaceutical Preparation Manufacturing		
SIC:	2834; Pharmaceutical Preparations		
Area:	~33-acre lot; ~6-acre plant		
Number Employees:	~190 (including regulars, contractors, and temps)		
Personnel participating in the inspection:			
Name	Affiliation	Title	Contact Information
Carlos J. Colombani	EPA Region 2 CEPD	Enforcement Officer	787-977-5862; colombani.carlos@epa.gov
Cary A. Ramos	Aurobindo, Inc	Facilities Engineer & EHS Manager	787-905-7780 cary.ramos@auoprinc.com
Anacelis Rodriguez	Aurobindo, Inc	HR Manager	787-905-7503 anacelisrodriguez@auoprinc.com
Gilberto Rodriguez	Aurobindo, Inc	EHS Specialist	
Status:	Final		
Record Schedule:	1044(c)		

Resource Conservation and Recovery Act
Auro PR, Inc. – Caguas
PRD987369766

EPA Inspector Signature/Date	 Digitally signed by CARLOS COLOMBANI DN: c=US, o=U.S. Government, ou=Environmental Protection Agency, cn=CARLOS COLOMBANI, 0.9.2342.19200300.100.1.1=68001003667 785 Date: 2023.09.25 10:07:37 -04'00' Adobe Acrobat version: 2023.006.20320 Carlos Josue Colombani Enforcement Officer
Supervisor Signature/Date	 DAVID CUEVAS- MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2023.09.25 10:18:56 -04'00' David N. Cuevas Miranda, Ph.D.

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1 INTRODUCTION

On August 30, 2023, a Resource Conservation and Recovery Act (RCRA) Subtitle C Compliance Evaluation Inspection (CEI) was conducted at Auro PR, Inc. – Caguas, (the Facility), pursuant to Section 3007 of RCRA. As part of the inspection, an opening conference, walkthrough, document review and closing conference were conducted to evaluate the Facility's compliance with the requirements that govern hazardous waste generators, universal waste handlers and used oil generators, as applicable.

The Facility is located at Caguas West Industrial Park Lot 24B PR-156 KM 58.8, Caguas, Puerto Rico, 00725. See aerial photograph (Figure 1) below for reference.



Figure 1: Auro PR, Inc. - Caguas Aerial Photograph

The purpose of this inspection was to evaluate the Facility's compliance with the RCRA requirements for hazardous waste management. Based on EPA's RCRAInfo database, the Facility is listed as a large quantity generator (LQG) of hazardous waste and was last inspected by EPA on August 1, 2018. Under EPA Policy, LQGs are required to be inspected every 5 (five) years, and thus, an inspection was due in August of 2023. The inspection was unannounced.

2 OPENING CONFERENCE

I met with Ms. Cary A. Ramos, Facilities Engineer and Environmental, Health and Safety Manager, and Ms. Anacelis Rodriguez, Human Resources Manager, for the opening conference. I identified myself as an EPA RCRA enforcement officer, told the Facility representatives the purpose of the inspection, and offered Ms. Ramos and Ms. Rodriguez an opportunity to claim confidential business information (CBI).

I then proceeded to request documents that would be needed to complete the compliance evaluation. These were the following:

- Hazardous waste manifests;
- Land disposal restrictions;
- RCRA personnel training records;
- Contingency Plan;
- Quick reference guide;
- Biennial report; and
- Weekly inspections.

I also explained the areas that required a visit to ensure compliance with the regulations. A plan was put in place to ensure these areas were inspected during the walkthrough.

2.1 FACILITY BACKGROUND AND OPERATION

Aurobindo Pharma Limited is a multinational pharmaceutical manufacturing company headquartered in India. It manufactures generic pharmaceuticals and active pharmaceutical ingredients. The major therapeutic and product areas are antibiotics, anti-retrovirals, cardiovascular products, central nervous system products, gastroenterological, and anti-allergics.

In 2021, Aurobindo Pharma Limited established operations in Puerto Rico (PR) under the name Auro PR, Inc. It acquired a 240,000 (two hundred and forty thousand) square foot pharmaceutical manufacturing plant in Caguas, PR (the Facility) that was owned by Mylan, LLC. The acquisition is expected to generate approximately 500 (five hundred) jobs in the first 3 (three) to 5 (five) years of operation. The products that will be manufactured in PR will be sold first in the United States and later in more countries.

The Facility is designed to manufacture oral solid dose products, both tablets and capsules, with both regular and high potency capabilities. It consists of 5 (five) packaging lines, 4 (four) laboratories (Raw Materials, Finished Products, Microbiology and Quality Control) and a warehouse for receiving, sampling, dispensing, storing, and shipping.

Since June 2023, the Facility ceased its manufacturing operations to undergo a plant modernization causing a reduction in the workforce. The construction/renovation project is expected to be completed sometime in 2026. The Facility aims in producing between 250 (two hundred and fifty) and 300 (three hundred) million tablets a month versus the 30 (thirty) to 40 (forty) that were being produced with its current infrastructure. Ms. Ramos stated that due to the operation pause, several RCRA documents were stored in boxes and/or sent off-site for record management but they would be gathered and sent electronically to EPA.

The Facility representatives reported that the plant currently employs approximately 190 (one hundred and ninety) people that are composed by regular employees, contractors, and temps. Auro Pr, Inc covers an area of about 15.3 (thirty) acres of land.

2.2 SOLID AND HAZARDOUS WASTE GENERATION

Up until June 2023, the Facility was manufacturing oral solid dose products, both tablets and capsules, with both regular and high potency capabilities. This process, in addition to its laboratories, were generating hazardous and nonhazardous waste. After pausing the operation, the Facility is no longer generating hazardous waste from the production lines because products are not being manufactured. Production is expected to restart in 2026 which is when the project is expected to be completed.

Auro Pr, Inc is still generating hazardous and nonhazardous waste from several satellite accumulation areas (SAAs) in laboratories and accumulates its hazardous and nonhazardous waste in a central accumulation area (CAA). The SAAs are located in the Finished Product Laboratory and in the Quality Control Laboratory. The Facility's dedicated hauler is Clean Harbors.

Majority of the hazardous waste that has been generated is shipped under waste codes D001 (ignitable), D002 (corrosive), F-listed spent solvents and F-listed spent nonhalogenated solvents, P-listed acute hazardous waste from discarded commercial chemical products, U-listed hazardous waste from discarded commercial chemical products, benzene, pyridine, and chromium. Its P-listed waste are mainly P030 (soluble cyanides salts) and P098 (potassium cyanide).

3 FACILITY WALKTHROUGH

Ms. Ramos accompanied me during the facility walkthrough. The following areas were inspected for compliance:

- Finished Products Laboratory SAA;
- Quality Control Laboratory SAA; and
- CAA.

The observations for each area are described below.

3.1 SATELLITE ACCUMULATION AREAS (SAAs)

As mentioned above, the Finished Product Laboratory and the Quality Control Laboratory SAAs were visited to evaluate compliance with the RCRA regulations.

At the time of the inspection, the Finished Product Laboratory SAA had a 55-gallon drum of laboratory waste mixed with spent solvents and 2 (two) hazardous waste containers of laboratory dissolution hydrochloric acid (HCL) (See Appendix A, Photographs 1 and 2).

At the Quality Control Laboratory SAA, there was a hazardous waste container of dissolution HCL, 2 (two) 55-gallon drums of laboratory waste mixed with spent solvents and a 55-gallon drum of laboratory dissolution HCL (See Appendix A, Photographs 3 and 4).

The hazardous waste containers at the SAAs that I visited were properly labeled with the words “hazardous waste”, with an indication of the nature of the hazard being stored, and at or near the point of generation.

3.2 CENTRAL ACCUMULATION AREA (CAA)

Mr. Gilberto Rodriguez, Environmental, Health and Safety Specialist, joined for this portion of the walkthrough.

At the time of the inspection, 24 (twenty-four) 30-gallon drums of buspirone hydrochloride (UN2811 toxic solid, organic, not otherwise specified [N.O.S.]) labeled as toxic were awaiting hazardous waste determination. The accumulation time of the drums was unclear given there were no accumulation start date labels on any drum. See Appendix A, Photographs 5, 6, and 7.

The CAA was also storing the following hazardous waste:

- 2 (two) 55gallon drums of laboratory dissolution HCL both dated June 19, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated June 26, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated June 29, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated June 30, 2023;
- a 55-gallon drum of absorbent material with contaminated isopropyl alcohol (IPA) dated June 30, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated July 7, 2023;
- a 55gallon drum of laboratory dissolution HCL dated July 7, 2023;
- a 55-gallon drum of spent IPA 70% dated July 7, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated July 13, 2023;
- a container of corrosive waste dated July 14, 2023;
- a 55gallon drum of laboratory dissolution HCL dated July 18, 2023;
- a 55-gallon drum of absorbent material with contaminated IPA dated July 24. 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated July 24, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated July 27, 2023;
- a container of spent IPA 70% dated August 2, 2023;
- a 55-gallon drum of spent IPA 70% dated August 2, 2023;
- a container of isopar g fluid dated August 3, 2023;
- a container of isopar g fluid (a viscosity reducing agent) dated August 3, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated August 3, 2023;
- a 55-gallon drum of absorbent material with contaminated IPA dated August 4, 2023;
- a 55-gallon drum of spent IPA 70% dated August 10, 2023;
- a 55gallon drum of lab dissolution HCL dated August 11, 2023;
- a container of acetonitrile and methanol dated August 11, 2023;
- a container of isopar g fluid dated August 14, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated August 14, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated August 14, 2023;
- a 55-gallon drum of laboratory waste (mixture of spent solvents) dated August 24, 2023; and
- a 55gallon drum of laboratory dissolution HCL dated August 24, 2023.

At the time of the inspection, the CAA had emergency spill kits and an eye washing station readily available, a telephone at reach in case emergency protocols had to be activated, fire extinguishers present, the emergency contact information signage posted, and adequate aisle space to conduct a thorough inspection of the hazardous waste drums/containers (See Appendix A, Photographs 8, 9, 10 and 11).

The hazardous waste in the CAA was not over the 90-day on-site accumulation limit an LQG is allowed without having a storage facility permit.

3.3 USED OIL STORAGE

According to Ms. Ramos, the Facility does not generate used oil.

3.4 UNIVERSAL WASTE STORAGE AREA

While the Facility has a dedicated area for used fluorescent bulbs and batteries, at the time of the inspection, universal waste was not being accumulated nor generated.

4 DOCUMENT REVIEW

During the inspection, I requested the documents listed under Section 2 of this report. Below are the observations noted after the document review was completed on and off-site.

Weekly Inspections

CAA

The Facility provided CAA weekly inspection records for calendar years 2020, 2021, 2022 and 2023 (January through July) The inspection checklist includes checking for leaking containers and for deterioration of containers caused by corrosion or other factors, and for proper hazardous waste labels and accumulation start dates.

Contingency Plan

The Facility does not have a contingency plan. The August 2018 contingency plan that was provided pertains to the prior plant owner, Mylan LLC. As mentioned in Section 2.1, in 2021, Aurobindo Pharma Limited established operations in Puerto Rico (PR) under the name Auro PR, Inc when it acquired Mylan LLC's plant in Caguas, PR.

Quick reference guide

The Facility does not have a quick reference guide. The August 2018 quick reference guide that was provided pertains to the prior plant owner, Mylan LLC. As mentioned in Section 2.1, in 2021, Aurobindo Pharma Limited established operations in Puerto Rico (PR) under the name Auro PR, Inc when it acquired Mylan LLC's plant in Caguas, PR.

Personnel Training

Annual RCRA personnel training was provided for Mr. Miguel Pedraza, Mr. Gilberto Rodriguez, and Mr. Jose Muñoz for calendar year 2020. The Facility also provided the RCRA waste management training material slides that are used for annual refreshers.

RCRA personnel training for calendar years 2021 and 2022 were not provided. Documents were not provided for job titles and written descriptions of type and amount of introductory and continuing training needed for personnel associated with the Facility's hazardous waste management.

Manifests

All the hazardous waste manifests that were provided had proper land disposal restriction notification forms based on the shipped waste codes and were processed into EPA's Hazardous Waste Electronic Manifest System (e-Manifest). Hazardous waste manifests from January 2022 through September 2022 were not provided by the Facility. Based on e-Manifest, the following manifest tracking numbers were shipped between January 2022 through September 2022:

- 015721541FLE shipped on January 27, 2022;
- 015721452FLE shipped on January 27, 2022;
- 017088351FLE shipped on January 27, 2022;
- 017088383FLE shipped on February 25, 2022
- 017088430FLE shipped on March 31, 2022;
- 015271790FLE shipped on May 12, 2022;
- 015721791FLE shipped on May 12, 2022;
- 015721829FLE shipped on May 12, 2022;
- 017086954FLE shipped on July 1, 2022
- 017088354FLE shipped on July 1, 2022;
- 017087339FLE shipped on August 25, 2022;
- 017087343FLE shipped on August 25, 2022;
- 017087344FLE shipped on August 25, 2022; and
- 017086162FLE shipped on September 8, 2022.

The Facility did not have a copy of the manifest with the handwritten signature of the owner or operator of the designated facility for the following hazardous waste manifest tracking numbers:

- 015728964FLE shipped on November 17, 2022;
- 015728992FLE shipped on November 17, 2022;
- 01899452FLE shipped on May 26, 2023; and
- 018199181FLE shipped on June 15, 2023.

Note, a generator of 1,000 (one thousand) kilograms or greater of hazardous waste and/or greater than 1 (one) kg of acute hazardous waste in a calendar month that does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 (thirty-five) days of the date the waste was accepted by the initial transporter must contact the transporter and/or the owner or operator of the designated facility to determine the status of the hazardous waste.

In addition, an Exception Report must be submitted to the EPA Regional Administrator for the Region in which the generator is located if a copy of the manifest with the handwritten signature of the owner or operator of the designated facility is not received within 45 (forty-five) days of the date the waste was accepted by the initial transporter.

Manifest Tracking Number	Date of Shipment	Days Since Shipment/Inspection Date
015728964FLE	November 17, 2022	287 days
015728992FLE	November 17, 2022	287 days
01899452FLE	May 26, 2023	97 days
018199181FLE	June 15, 2023	77 days

In 2020, the Facility shipped approximately 49,189 kilograms of hazardous waste, and 10 kilograms of acute hazardous waste. In 2021, it shipped approximately 48,804 kilograms of hazardous waste, and 5 kilograms of acute hazardous waste. In 2022, the Facility shipped approximately 35,274 kilograms of hazardous waste, and 3 kilograms of acute hazardous waste. So far, in 2023, the Facility has shipped approximately 16,747 kilograms of hazardous waste and 7 kilograms of acute hazardous waste (from January through June of 2023).

Thus, based on the manifests reviewed for the past three years, and conversations with the Facility representatives, it appears that the Facility routinely generated more than 1,000 kg per month of hazardous waste. Consequently, the Facility appears to be correctly classified as a LQG.

The following table summarizes the amount of non-acute and acute hazardous waste shipped by calendar year.

Manifest Year	Acute?	Amount of Waste (kg)
2020	Acute	10
2020	Non-Acute	49189
2021	Acute	5
2021	Non-Acute	48804
2022	Acute	3
2022	Non-Acute	35274
2023	Acute	7
2023	Non-Acute	16747

Up until the operations ceased in June 2023, Auro PR, Inc – Caguas used to ship its hazardous waste every 2 (two) or 3 (three) months but often sooner given the amount that was being generated.

Biennial Report

The Facility provided proof of its Biennial Report submission. This was verified in RCRAInfo for the reporting cycle of calendar year 2021. The report was received on February 21, 2022.

5 CLOSING CONFERENCE

On August 30, 2023, after completion of the walkthrough and onsite document review, I met with Ms. Ramos to conduct a closing conference. I indicated that the purpose of the closing conference was to inform the Facility about the CEI observations and the opportunity to clarify any questions or doubts the representative might have pertaining the RCRA inspection. I also communicated that a CEI report would be emailed once finalized.

6 POTENTIAL AREAS OF CONCERN

Based on observations made during the walkthrough of the Facility and/or a review of records provided to EPA by the Facility on-site and/or afterwards, the following potential areas of concern were identified:

REGULATORY, STATUTORY OR PERMIT REFERENCE	FIELD OBSERVATION
RCRA Subtitle C – Hazardous Waste	
40 CFR § Part 262.11(a) : The hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste such that the RCRA classification of the waste may change.	At the time of the inspection, 24 (twenty-four) 30-gallon drums of buspirone hydrochloride (UN2811 toxic solid, organic, not otherwise specified [N.O.S.]) labeled as toxic were awaiting hazardous waste determination. The accumulation time of the drums was unclear given there were no accumulation start date labels on any drum. See Appendix A, Photographs 5, 6 and 7).
40 CFR § Part 262.260(a) : A large quantity generator must have a contingency plan for the facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water.	The Facility provided a contingency plan for Mylan LLC (prior plant owner/operator) dated August 2018, not for Auro PR, Inc – Caguas.

REGULATORY, STATUTORY OR PERMIT REFERENCE	FIELD OBSERVATION
40 CFR § Part 262.262(b): Prepares a quick reference guide and submits it to emergency response agencies.	The Facility provided a quick reference guide for Mylan LLC (prior plant owner/operator) dated August 2018, not for Auro PR, Inc – Caguas.
40 CFR § Part 262.17(a)(7)(iii): Facility personnel must take part in an annual review of the initial training required in paragraph (a)(7)(i) of this section.	The Facility provided RCRA personnel training records for Mr. Pedraza, Mr. Rodriguez, and Mr. Muñoz for calendar year 2020. RCRA personnel training for calendar years 2021 and 2022 were not provided.
40 CFR § Part 262.17(a)(7)(iv): Tracks specific job titles and names of persons filling positions. Describe, in writing, skills, education, or qualification, and duties associated with each job title. Prepares written description of type and amount of introductory and continuing training.	Documents were not provided for job titles, persons filling positions, and written descriptions of type and amount of introductory and continuing training needed for personnel associated with the Facility’s hazardous waste management.
40 CFR § Part 262.40(a): A generator must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until he receives a signed copy from the designated facility which received the waste. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.	Based on e-Manifest, the following manifest tracking numbers were shipped between January 2022 through September 2022 but were not provided by the Facility: • 015721541FLE shipped on January 27, 2022; • 015721452FLE shipped on January 27, 2022; • 017088351FLE shipped on January 27, 2022; • 017088383FLE shipped on February 25, 2022 • 017088430FLE shipped on March 31, 2022; • 015271790FLE shipped on May 12, 2022; • 015721791FLE shipped on May 12, 2022; • 015721829FLE shipped on May 12, 2022; • 017086954FLE shipped on July 1, 2022 • 017088354FLE shipped on July 1, 2022; • 017087339FLE shipped on August 25, 2022; • 017087343FLE shipped on August 25, 2022; • 017087344FLE shipped on August 25, 2022; and • 017086162FLE shipped on September 8, 2022.
40 CFR § Part 262.42(a)(1): A generator of 1,000 kilograms or greater of hazardous waste in a calendar month, or	The Facility did not have a copy of the manifest with the handwritten signature of the owner or operator of the

REGULATORY, STATUTORY OR PERMIT REFERENCE	FIELD OBSERVATION															
greater than 1 kg of acute hazardous waste listed in § 261.31 or § 261.33(e) in a calendar month, who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the waste was accepted by the initial transporter must contact the transporter and/or the owner or operator of the designated facility to determine the status of the hazardous waste.	designated facility for the following hazardous waste manifest tracking numbers: <table><tr><th>Manifest Tracking Number</th><th>Date of Shipment</th><th>Days Since Shipment/Inspection Date</th></tr><tr><td>015728964FLE</td><td>November 17, 2022</td><td>287 days</td></tr><tr><td>015728992FLE</td><td>November 17, 2022</td><td>287 days</td></tr><tr><td>01899452FLE</td><td>May 26, 2023</td><td>97 days</td></tr><tr><td>018199181FLE</td><td>June 15, 2023</td><td>77 days</td></tr></table>	Manifest Tracking Number	Date of Shipment	Days Since Shipment/Inspection Date	015728964FLE	November 17, 2022	287 days	015728992FLE	November 17, 2022	287 days	01899452FLE	May 26, 2023	97 days	018199181FLE	June 15, 2023	77 days
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018199181FLE	June 15, 2023	77 days														
40 CFR § Part 262.42(a)(2) : A generator of 1,000 kilograms or greater of hazardous waste in a calendar month, or greater than 1 kg of acute hazardous waste listed in § 261.31 or § 261.33(e) in a calendar month, must submit an Exception Report to the EPA Regional Administrator for the Region in which the generator is located if he has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter. The Exception Report must include: a legible copy of the manifest for which the generator does not have confirmation of delivery; a cover letter signed by the generator or his authorized representative explaining the efforts taken to locate the hazardous waste and the results of those efforts.	The Facility did not have a copy of the manifest with the handwritten signature of the owner or operator of the designated facility which are more than 45 (forty-five) days from the date the waste was accepted by the initial transporter nor an Exception Report for the following hazardous waste manifest tracking numbers: <table><tr><th>Manifest Tracking Number</th><th>Date of Shipment</th><th>Days Since Shipment/Inspection Date</th></tr><tr><td>015728964FLE</td><td>November 17, 2022</td><td>287 days</td></tr><tr><td>015728992FLE</td><td>November 17, 2022</td><td>287 days</td></tr><tr><td>01899452FLE</td><td>May 26, 2023</td><td>97 days</td></tr><tr><td>018199181FLE</td><td>June 15, 2023</td><td>77 days</td></tr></table>	Manifest Tracking Number	Date of Shipment	Days Since Shipment/Inspection Date	015728964FLE	November 17, 2022	287 days	015728992FLE	November 17, 2022	287 days	01899452FLE	May 26, 2023	97 days	018199181FLE	June 15, 2023	77 days
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7 ENVIRONMENTAL ASSISTANCE

Based on the observations made during the inspection, the Facility should consider the following resources to increase their understanding and compliance with applicable environmental requirements and/or go ‘beyond compliance’ to reduce its overall environmental footprint:

- Final Rule: Hazardous Waste Generator Improvements (2017),
<https://www.epa.gov/hwgenerators/final-rule-hazardous-waste-generator-improvements>
- Compliance Assistance Centers,
<https://www.complianceassistance.net/>
- Hazardous Waste Portal, and
<https://www.hazwasteportal.org/>
- Fact Sheet on Requirements for Large Quantity Generators of Hazardous Waste,
https://www.epa.gov/sites/default/files/2020-07/documents/10635_lqg-factsheet_508.pdf

8 APPENDICES

- A. Inspection Photographs
- B. Hazardous Waste Manifests
- C. EJScreen Report
- D. Flood Zone Map

Appendix A: Inspection Photos



Photograph 1: A 55-gallon drum of laboratory waste mixed with spent solvents in the Finished Product Laboratory SAA.



Photograph 2: 2 (two) hazardous waste containers of laboratory dissolution HCL in the Finished Product Laboratory SAA.



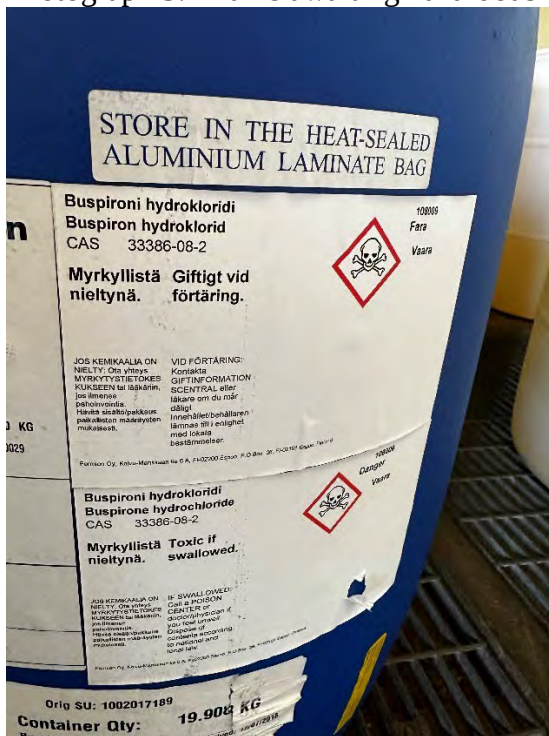
Photograph 3: A 55-gallon drum of laboratory dissolution HCL in the Quality Control Laboratory SAA.



Photograph 4: 2-55-gallon drums of laboratory waste mixed with spent solvents and a hazardous waste container of dissolution HCL in the Quality Control Laboratory SAA.



Photograph 5: Drums awaiting hazardous waste determination in the CAA.



Photograph 6: 55-gallon drum of buspironi hydrochloride in the CAA.



Photograph 7: 55-gallon drum of buspirone hydrochloride in the CAA.



Photograph 8: Emergency signage outside the CAA.



Photograph 9: Fire extinguisher outside the CAA.



Photograph 10: Fire alarm outside the CAA.



Photograph 11: Emergency equipment outside the CAA.

Appendix B: Hazardous Waste Manifests

Manifest Date	Waste (kg)	Manifest Tracking Number
6/15/2023	1,267	018199181FLE
6/15/2023	2,504	018199181FLE
6/15/2023	91	018199181FLE
6/15/2023	1,252	018199181FLE
5/26/2023	2	018199452FLE
5/26/2023	2	018199452FLE
5/26/2023	2	018199452FLE
5/26/2023	41	018199452FLE
5/26/2023	27	018199452FLE
5/26/2023	19	018199452FLE
5/26/2023	2	018199452FLE
5/26/2023	5	018199452FLE
5/26/2023	6	018199452FLE
5/26/2023	0	018199452FLE
4/13/2023	6	017848431FLE
4/13/2023	1,167	018199120FLE
4/13/2023	2,712	018199120FLE
4/13/2023	23	017848431FLE
4/13/2023	68	018199120FLE
4/13/2023	22	017848431FLE
4/13/2023	12	017848431FLE
4/13/2023	835	018199120FLE
4/13/2023	2	017848431FLE
4/13/2023	6	017848431FLE
2/9/2023	1,099	017846890FLE
2/9/2023	837	017848141FLE
2/9/2023	12	017848141FLE
2/9/2023	3,180	017846890FLE
2/9/2023	34	017846890FLE
2/9/2023	16	017848141FLE
2/9/2023	1,461	017846890FLE
2/9/2023	14	017848141FLE
2/9/2023	2	017848141FLE
2/9/2023	0	017848141FLE
2/9/2023	1	017848141FLE
2/9/2023	23	017848141FLE
2/9/2023	1	017848141FLE

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11/17/2022	10	015728964FLE
11/17/2022	1,322	015728992FLE
11/17/2022	5	015728964FLE
11/17/2022	2	015728964FLE
11/17/2022	4	015728964FLE
11/17/2022	41	015728964FLE
11/17/2022	2,295	015728992FLE
11/17/2022	112	015728992FLE
11/17/2022	48	015728964FLE
11/17/2022	1,043	015728992FLE
11/17/2022	2	015728964FLE
11/17/2022	4	015728964FLE
11/17/2022	0	015728964FLE
11/17/2022	5	015728964FLE
11/17/2022	27	015728964FLE
11/17/2022	2	015728964FLE
11/17/2022	2	015728964FLE
9/8/2022	1	017086162FLE
9/8/2022	2	017086162FLE
8/25/2022	835	017087339FLE
8/25/2022	410	017087343FLE
8/25/2022	4	017087344FLE
8/25/2022	5	017087344FLE
8/25/2022	19	017087344FLE
8/25/2022	2,921	017087339FLE
8/25/2022	31	017087339FLE
8/25/2022	113	017087344FLE
8/25/2022	1,461	017087339FLE
8/25/2022	8	017087344FLE
8/25/2022	0	017087344FLE
8/25/2022	19	017087344FLE
8/25/2022	1	017087344FLE
8/25/2022	1	017087344FLE
8/25/2022	0	017087344FLE
8/25/2022	0	017087344FLE
8/25/2022	1	017087344FLE
7/1/2022	1,613	017086954FLE
7/1/2022	2,712	017086954FLE
7/1/2022	120	017086954FLE

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7/1/2022	1,043	017086954FLE
5/12/2022	1,225	015721829FLE
5/12/2022	5	015721790FLE
5/12/2022	4	015721790FLE
5/12/2022	6	015721790FLE
5/12/2022	11	015721790FLE
5/12/2022	2	015721790FLE
5/12/2022	2	015721790FLE
5/12/2022	10	015721790FLE
5/12/2022	2,295	015721829FLE
5/12/2022	209	015721829FLE
5/12/2022	48	015721790FLE
5/12/2022	20	015721790FLE
5/12/2022	1,043	015721829FLE
5/12/2022	1	015721790FLE
5/12/2022	0	015721790FLE
5/12/2022	0	015721790FLE
5/12/2022	3	015721790FLE
5/12/2022	7	015721790FLE
5/12/2022	2	015721791FLE
5/12/2022	0	015721790FLE
3/31/2022	1,551	017088430FLE
3/31/2022	2,295	017088430FLE
3/31/2022	69	017088430FLE
3/31/2022	1,354	017088430FLE
2/25/2022	1,045	017088383FLE
2/25/2022	2,295	017088383FLE
2/25/2022	38	017088383FLE
2/25/2022	1,043	017088383FLE
1/27/2022	8	015721541FLE
1/27/2022	895	017088351FLE
1/27/2022	217	017088354FLE
1/27/2022	1	015721542FLE
1/27/2022	23	015721541FLE
1/27/2022	1,936	017088351FLE
1/27/2022	34	015721541FLE
1/27/2022	68	017088351FLE
1/27/2022	9	015721541FLE
1/27/2022	1,252	017088351FLE

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12/15/2021	66	015158653FLE
12/15/2021	1,459	015721972FLE
12/15/2021	359	015721973FLE
12/15/2021	11	015158653FLE
12/15/2021	4	015158653FLE
12/15/2021	2,504	015721972FLE
12/15/2021	59	015158653FLE
12/15/2021	38	015721972FLE
12/15/2021	41	015158653FLE
12/15/2021	1,252	015721972FLE
12/15/2021	5	015158653FLE
12/15/2021	0	015158653FLE
12/15/2021	4	015158653FLE
12/15/2021	0	015158653FLE
10/28/2021	301	015721977FLE
10/28/2021	346	015721979FLE
10/28/2021	1,878	015721977FLE
10/28/2021	35	015721977FLE
10/28/2021	835	015721977FLE
9/30/2021	4	016425125FLE
9/30/2021	930	016425232FLE
9/30/2021	386	016425235FLE
9/30/2021	2,295	016425232FLE
9/30/2021	49	016425232FLE
9/30/2021	25	016425125FLE
9/30/2021	1,461	016425232FLE
9/30/2021	9	016425232FLE
9/30/2021	2	016425125FLE
9/30/2021	2	016425125FLE
9/30/2021	1	016425125FLE
9/30/2021	2	016425125FLE
9/30/2021	0	016425125FLE
9/30/2021	8	016425125FLE
8/26/2021	15	015722734FLE
8/26/2021	621	016425084FLE
8/26/2021	4	015722734FLE
8/26/2021	1,669	016425084FLE
8/26/2021	86	016425084FLE
8/26/2021	54	015722734FLE

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8/26/2021	0	015722734FLE
8/26/2021	5	015722734FLE
8/26/2021	785	016425084FLE
8/26/2021	20	015722734FLE
8/26/2021	2	015722734FLE
8/26/2021	20	015722734FLE
8/26/2021	2	015722734FLE
8/26/2021	4	015722734FLE
7/29/2021	1,067	016434334FLE
7/29/2021	336	016434335FLE
7/29/2021	1,878	016434334FLE
7/29/2021	93	016434334FLE
7/29/2021	1,252	016434334FLE
7/1/2021	5	015722778FLE
7/1/2021	1,500	016434280FLE
7/1/2021	5	015722778FLE
7/1/2021	2,391	016434280FLE
7/1/2021	17	015722778FLE
7/1/2021	33	016434280FLE
7/1/2021	12	015722778FLE
7/1/2021	835	016434280FLE
7/1/2021	3	015722778FLE
5/27/2021	1,056	015722461FLE
5/27/2021	4	015722434FLE
5/27/2021	1,252	015722461FLE
5/27/2021	27	015722461FLE
5/27/2021	29	015722434FLE
5/27/2021	27	015722434FLE
5/27/2021	1,043	015722461FLE
5/27/2021	1	015722434FLE
5/27/2021	6	015722434FLE
4/29/2021	1,429	015722494FLE
4/29/2021	422	015722495FLE
4/29/2021	113	015722623FLE
4/29/2021	8	015722623FLE
4/29/2021	0	015722623FLE
4/29/2021	12	015722623FLE
4/29/2021	1,878	015722494FLE
4/29/2021	24	015722494FLE

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4/29/2021	46	015722623FLE
4/29/2021	626	015722494FLE
4/29/2021	13	015722623FLE
4/29/2021	0	015722623FLE
4/29/2021	17	015722623FLE
4/29/2021	1	015722623FLE
4/29/2021	1	015722623FLE
3/25/2021	721	015456007FLE
3/25/2021	304	015456010FLE
3/25/2021	1,669	015456007FLE
3/25/2021	34	015456007FLE
3/25/2021	835	015456007FLE
2/25/2021	1,473	015455575FLE
2/25/2021	1	015455784FLE
2/25/2021	10	015455784FLE
2/25/2021	20	015455784FLE
2/25/2021	4	015455784FLE
2/25/2021	2,087	015455575FLE
2/25/2021	62	015455575FLE
2/25/2021	7	015455784FLE
2/25/2021	1,043	015455575FLE
2/25/2021	23	015455784FLE
2/25/2021	3	015455784FLE
1/13/2021	222	012253641FLE
1/13/2021	1,929	013822677FLE
1/13/2021	1	012253641FLE
1/13/2021	2,087	013822677FLE
1/13/2021	33	013822677FLE
1/13/2021	12	012253641FLE
1/13/2021	1,043	013822677FLE
1/13/2021	18	013822677FLE
1/13/2021	20	012253641FLE
1/13/2021	1	012253641FLE
1/13/2021	24	012253641FLE
1/13/2021	0	012253641FLE
11/19/2020	1,191	013822639FLE
11/19/2020	10	014720006FLE
11/19/2020	53	013822641FLE
11/19/2020	5	014720006FLE

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11/19/2020	1,669	013822639FLE
11/19/2020	20	014720006FLE
11/19/2020	65	013822639FLE
11/19/2020	835	013822639FLE
11/19/2020	15	014720006FLE
11/19/2020	20	014720006FLE
10/22/2020	753	013822600FLE
10/22/2020	298	013822601FLE
10/22/2020	160	013822602FLE
10/22/2020	1,515	013822600FLE
10/22/2020	40	013822600FLE
10/22/2020	635	013822600FLE
9/24/2020	11	013486028FLE
9/24/2020	1,107	013822481FLE
9/24/2020	211	013822483FLE
9/24/2020	7	013486028FLE
9/24/2020	1	013486028FLE
9/24/2020	1	013486028FLE
9/24/2020	4	013486028FLE
9/24/2020	1,960	013822481FLE
9/24/2020	1	013486028FLE
9/24/2020	4	013486028FLE
9/24/2020	15	013486028FLE
9/24/2020	3	013486029FLE
9/24/2020	653	013822481FLE
9/24/2020	9	013486028FLE
9/24/2020	3	013486028FLE
9/24/2020	3	013486028FLE
8/27/2020	1,288	015158460FLE
8/27/2020	314	015158462FLE
8/27/2020	153	015158463FLE
8/27/2020	1,742	015158460FLE
8/27/2020	59	015158460FLE
8/27/2020	21	015158463FLE
8/27/2020	1,089	015158460FLE
8/3/2020	397	014727153FLE
8/3/2020	871	014727155FLE
8/3/2020	1,742	014727152FLE
8/3/2020	45	014727152FLE

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8/3/2020	1,306	014727152FLE
8/3/2020	5	014727151FLE
7/31/2020	8	014106691FLE
7/31/2020	16	014106691FLE
7/31/2020	3	014106691FLE
7/31/2020	2	014106691FLE
7/31/2020	1	014106691FLE
7/31/2020	7	014106691FLE
6/30/2020	567	013486087FLE
6/30/2020	1,041	014172804FLE
6/30/2020	8	013486089FLE
6/30/2020	0	013486089FLE
6/30/2020	2,658	014172801FLE
6/30/2020	27	013486089FLE
6/30/2020	36	014172801FLE
6/30/2020	2	013486089FLE
6/30/2020	16	013486089FLE
6/30/2020	1,524	014172801FLE
6/30/2020	14	013486089FLE
6/30/2020	32	014172801FLE
5/28/2020	4	013485995FLE
5/28/2020	1,157	014172731FLE
5/28/2020	428	014172732FLE
5/28/2020	57	014172736FLE
5/28/2020	11	013485995FLE
5/28/2020	1,742	014172731FLE
5/28/2020	22	013485995FLE
5/28/2020	45	014172731FLE
5/28/2020	136	014172736FLE
5/28/2020	16	014172731FLE
5/28/2020	29	013485995FLE
5/28/2020	871	014172731FLE
5/28/2020	13	013485995FLE
5/28/2020	10	013485995FLE
5/28/2020	0	013485995FLE
5/28/2020	1	013485995FLE
5/28/2020	15	013485995FLE
4/30/2020	1,225	014172719FLE
4/30/2020	781	014172721FLE

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4/30/2020	4	014172534FLE
4/30/2020	2,463	014172719FLE
4/30/2020	36	014172721FLE
4/30/2020	2	014172534FLE
4/30/2020	11	014172534FLE
4/30/2020	50	014172719FLE
4/30/2020	5	014172534FLE
4/30/2020	11	014172534FLE
4/30/2020	871	014172719FLE
4/30/2020	7	014172534FLE
3/26/2020	15	013485738FLE
3/26/2020	1,179	014172630FLE
3/26/2020	569	014172632FLE
3/26/2020	4	013485738FLE
3/26/2020	1,742	014172630FLE
3/26/2020	119	014172630FLE
3/26/2020	871	014172630FLE
3/26/2020	16	013485738FLE
2/27/2020	34	013486059FLE
2/27/2020	789	013822369FLE
2/27/2020	340	013822370FLE
2/27/2020	3	013486059FLE
2/27/2020	1,960	013822369FLE
2/27/2020	45	013822369FLE
2/27/2020	7	013486059FLE
2/27/2020	1,089	013822369FLE
2/27/2020	0	013486059FLE
2/27/2020	4	013486059FLE
2/27/2020	1	013486059FLE
1/30/2020	5	014106660FLE
1/30/2020	487	014173813FLE
1/30/2020	1,157	014173814FLE
1/30/2020	3	014106660FLE
1/30/2020	1,524	014173814FLE
1/30/2020	16	014106660FLE
1/30/2020	41	014173814FLE
1/30/2020	8	014106660FLE
1/30/2020	871	014173814FLE
1/30/2020	0	014106660FLE

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1/30/2020	4	014173813FLE
1/30/2020	0	014106660FLE
1/30/2020	0	014106660FLE
1/30/2020	1	014106660FLE

Appendix C: EJScreen Report

EJScreen Community Report

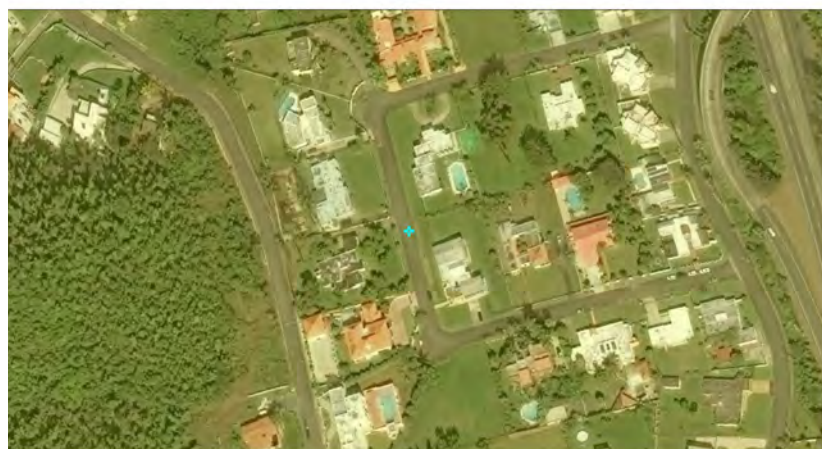
This report provides environmental and socioeconomic information for user-defined areas, and combines that data into environmental justice and supplemental indexes.

Caguas, PR

1 mile Ring Centered at 18.270691,-66.042506

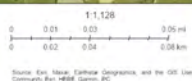
Population: 8,167

Area in square miles: 3.14



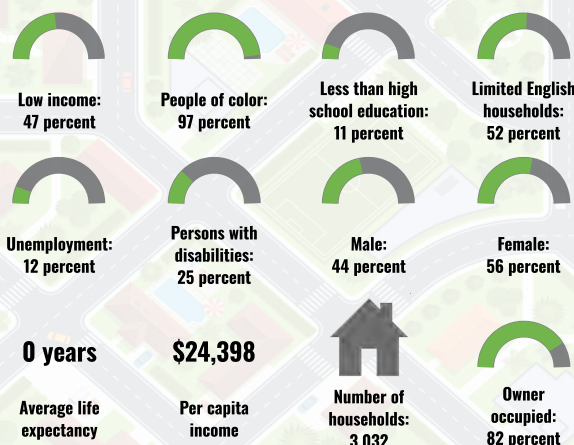
Oct 24, 2023

Aurorabdo - Caguas

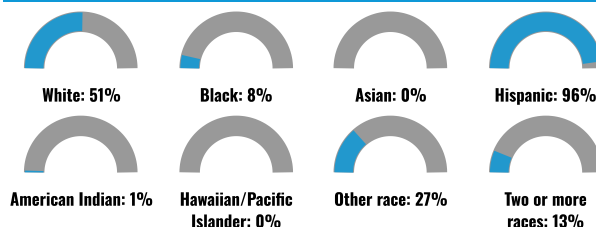


Source: Esri, DeLorme, Earthstar Geographics, and the GIS User Community, Esri, HERE, DeLorme, Swire, etc.

COMMUNITY INFORMATION



BREAKDOWN BY RACE



BREAKDOWN BY AGE



LIMITED ENGLISH SPEAKING BREAKDOWN



Notes: Numbers may not sum to totals due to rounding. Hispanic population can be of any race. Source: U.S. Census Bureau, American Community Survey (ACS) 2017-2021. Life expectancy data comes from the Centers for Disease Control.

LANGUAGES SPOKEN AT HOME

LANGUAGE	PERCENT
English	7%
Spanish	93%
Total Non-English	93%

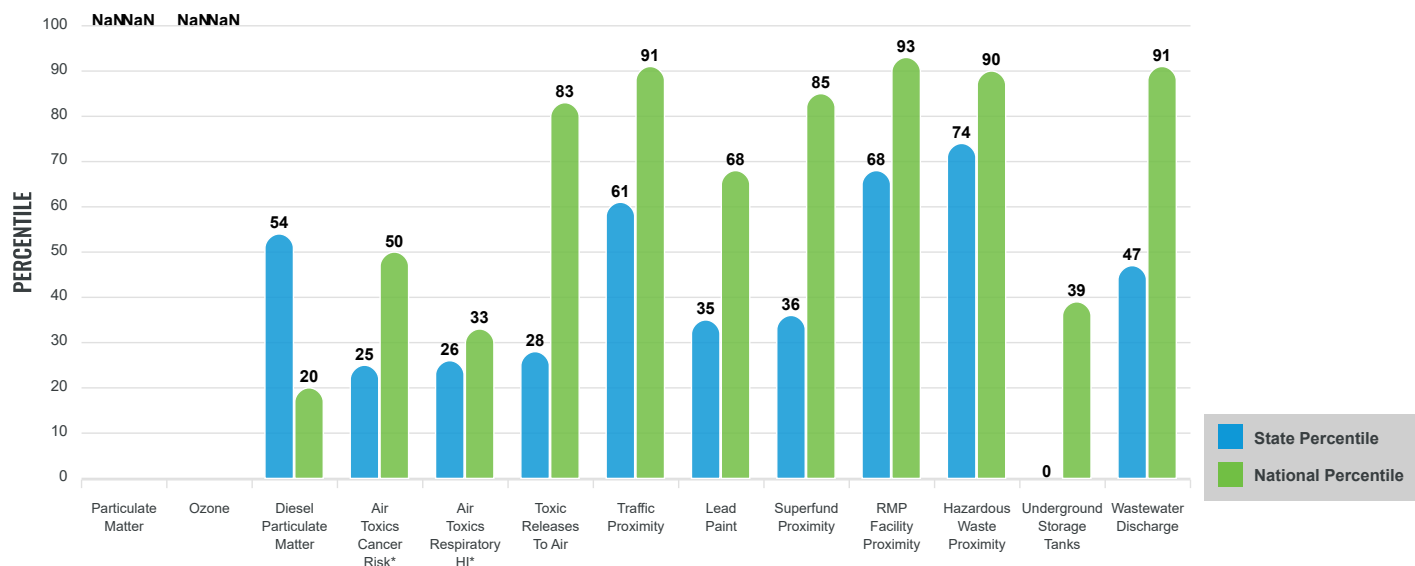
Environmental Justice & Supplemental Indexes

The environmental justice and supplemental indexes are a combination of environmental and socioeconomic information. There are thirteen EJ indexes and supplemental indexes in EJScreen reflecting the 13 environmental indicators. The indexes for a selected area are compared to those for all other locations in the state or nation. For more information and calculation details on the EJ and supplemental indexes, please visit the [EJScreen website](#).

EJ INDEXES

The EJ indexes help users screen for potential EJ concerns. To do this, the EJ index combines data on low income and people of color populations with a single environmental indicator.

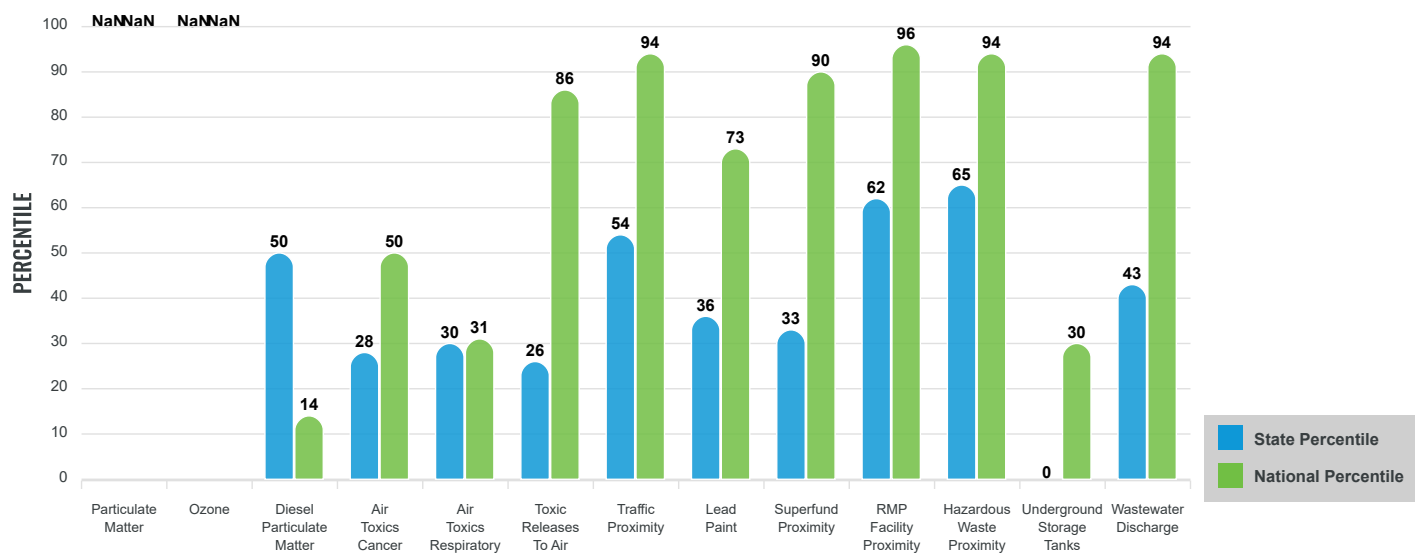
EJ INDEXES FOR THE SELECTED LOCATION



SUPPLEMENTAL INDEXES

The supplemental indexes offer a different perspective on community-level vulnerability. They combine data on percent low-income, percent linguistically isolated, percent less than high school education, percent unemployed, and low life expectancy with a single environmental indicator.

SUPPLEMENTAL INDEXES FOR THE SELECTED LOCATION



These percentiles provide perspective on how the selected block group or buffer area compares to the entire state or nation.

Report for 1 mile Ring Centered at 18.270691,-66.042506

EJScreen Environmental and Socioeconomic Indicators Data

SELECTED VARIABLES	VALUE	STATE AVERAGE	PERCENTILE IN STATE	USA AVERAGE	PERCENTILE IN USA
POLLUTION AND SOURCES					
Particulate Matter ($\mu\text{g}/\text{m}^3$)	N/A	N/A	N/A	8.08	N/A
Ozone (ppb)	N/A	N/A	N/A	61.6	N/A
Diesel Particulate Matter ($\mu\text{g}/\text{m}^3$)	0.0546	0.0667	62	0.261	4
Air Toxics Cancer Risk* (lifetime risk per million)	20	20	15	25	5
Air Toxics Respiratory HI*	0.2	0.19	17	0.31	4
Toxic Releases to Air	480	4,300	30	4,600	46
Traffic Proximity (daily traffic count/distance to road)	280	180	78	210	81
Lead Paint (% Pre-1960 Housing)	0.071	0.16	42	0.3	30
Superfund Proximity (site count/km distance)	0.067	0.15	40	0.13	53
RMP Facility Proximity (facility count/km distance)	0.62	0.47	77	0.43	80
Hazardous Waste Proximity (facility count/km distance)	1.7	0.76	86	1.9	71
Underground Storage Tanks (count/km ²)	0.33	1.7	60	3.9	35
Wastewater Discharge (toxicity-weighted concentration/m distance)	0.013	2.3	60	22	69
SOCIOECONOMIC INDICATORS					
Demographic Index	72%	83%	13	35%	91
Supplemental Demographic Index	31%	43%	16	14%	95
People of Color	97%	96%	13	39%	94
Low Income	47%	70%	13	31%	78
Unemployment Rate	12%	15%	50	6%	87
Limited English Speaking Households	52%	67%	17	5%	98
Less Than High School Education	11%	21%	24	12%	61
Under Age 5	4%	4%	61	6%	40
Over Age 64	25%	22%	63	17%	80
Low Life Expectancy	N/A	N/A%	N/A	20%	N/A

*Diesel particulate matter, air toxics cancer risk, and air toxics respiratory hazard index are from the EPA's Air Toxics Data Update, which is the Agency's ongoing, comprehensive evaluation of air toxics in the United States. This effort aims to prioritize air toxics, emission sources, and locations of interest for further study. It is important to remember that the air toxics data presented here provide broad estimates of health risks over geographic areas of the country, not definitive risks to specific individuals or locations. Cancer risks and hazard indices from the Air Toxics Data Update are reported to one significant figure and any additional significant figures here are due to rounding. More information on the Air Toxics Data Update can be found at: <https://www.epa.gov/haps/air-toxics-data-update>.

Sites reporting to EPA within defined area:

Superfund	0
Hazardous Waste, Treatment, Storage, and Disposal Facilities	1
Water Dischargers	8
Air Pollution	2
Brownfields	0
Toxic Release Inventory	2

Other community features within defined area:

Schools	1
Hospitals	0
Places of Worship	0

Other environmental data:

Air Non-attainment	No
Impaired Waters	Yes

Selected location contains American Indian Reservation Lands*	No
Selected location contains a "Justice40 (CEJST)" disadvantaged community	Yes
Selected location contains an EPA IRA disadvantaged community	Yes

Report for 1 mile Ring Centered at 18.270691,-66.042506

EJScreen Environmental and Socioeconomic Indicators Data

HEALTH INDICATORS

INDICATOR	HEALTH VALUE	STATE AVERAGE	STATE PERCENTILE	US AVERAGE	US PERCENTILE
Low Life Expectancy	N/A	-99999900%	N/A	20%	N/A
Heart Disease	N/A	-999999	N/A	6.1	N/A
Asthma	N/A	-999999	N/A	10	N/A
Cancer	N/A	-999999	N/A	6.1	N/A
Persons with Disabilities	22.4%	21.6%	54	13.4%	91

CLIMATE INDICATORS

INDICATOR	HEALTH VALUE	STATE AVERAGE	STATE PERCENTILE	US AVERAGE	US PERCENTILE
Flood Risk	N/A	-99999900%	N/A	12%	N/A
Wildfire Risk	N/A	-99999900%	N/A	14%	N/A

CRITICAL SERVICE GAPS

INDICATOR	HEALTH VALUE	STATE AVERAGE	STATE PERCENTILE	US AVERAGE	US PERCENTILE
Broadband Internet	13%	32%	15	14%	55
Lack of Health Insurance	7%	7%	62	9%	53
Housing Burden	No	N/A	N/A	N/A	N/A
Transportation Access	No	N/A	N/A	N/A	N/A
Food Desert	No	N/A	N/A	N/A	N/A

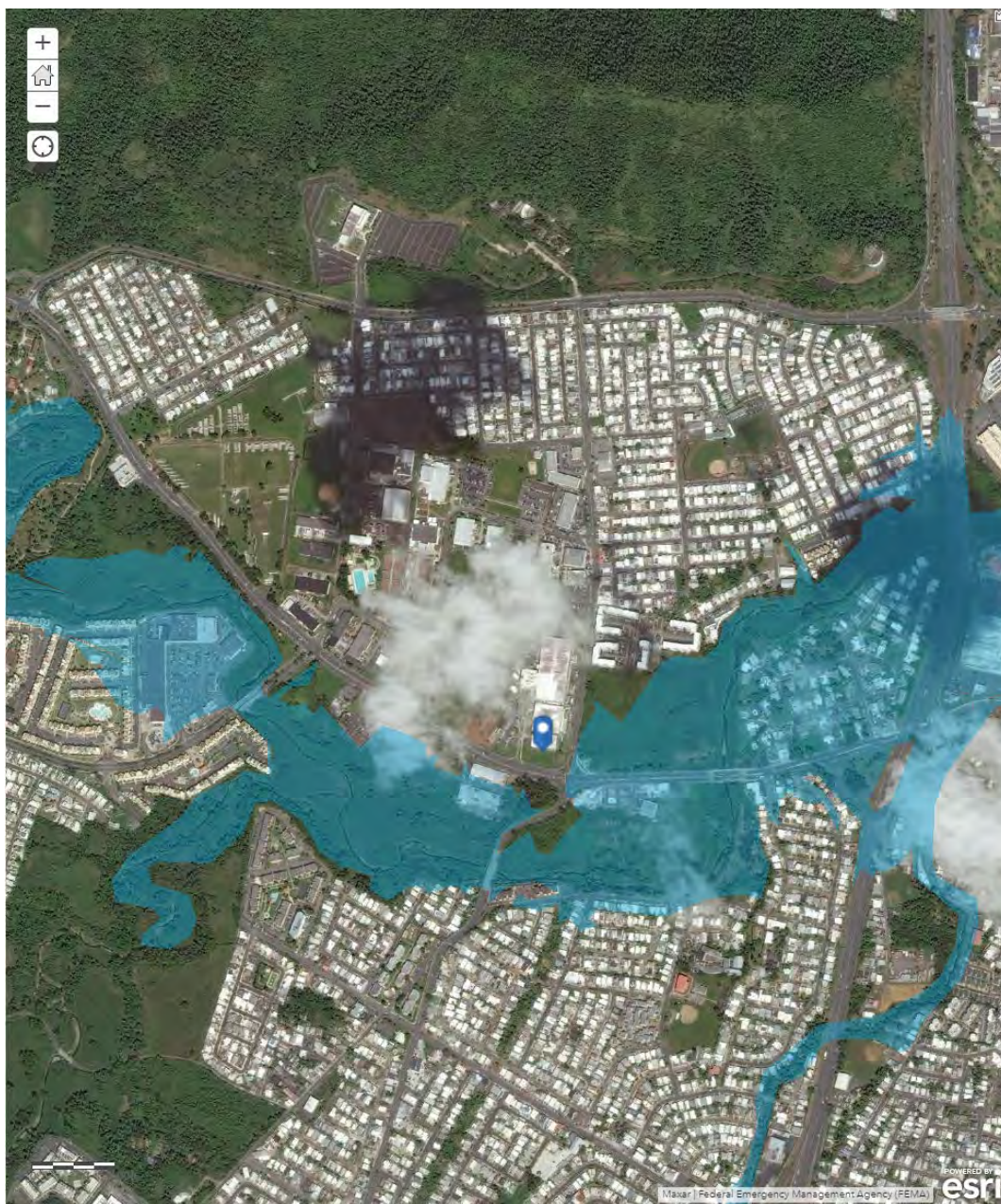
Footnotes

Report for 1 mile Ring Centered at 18.270691,-66.042506

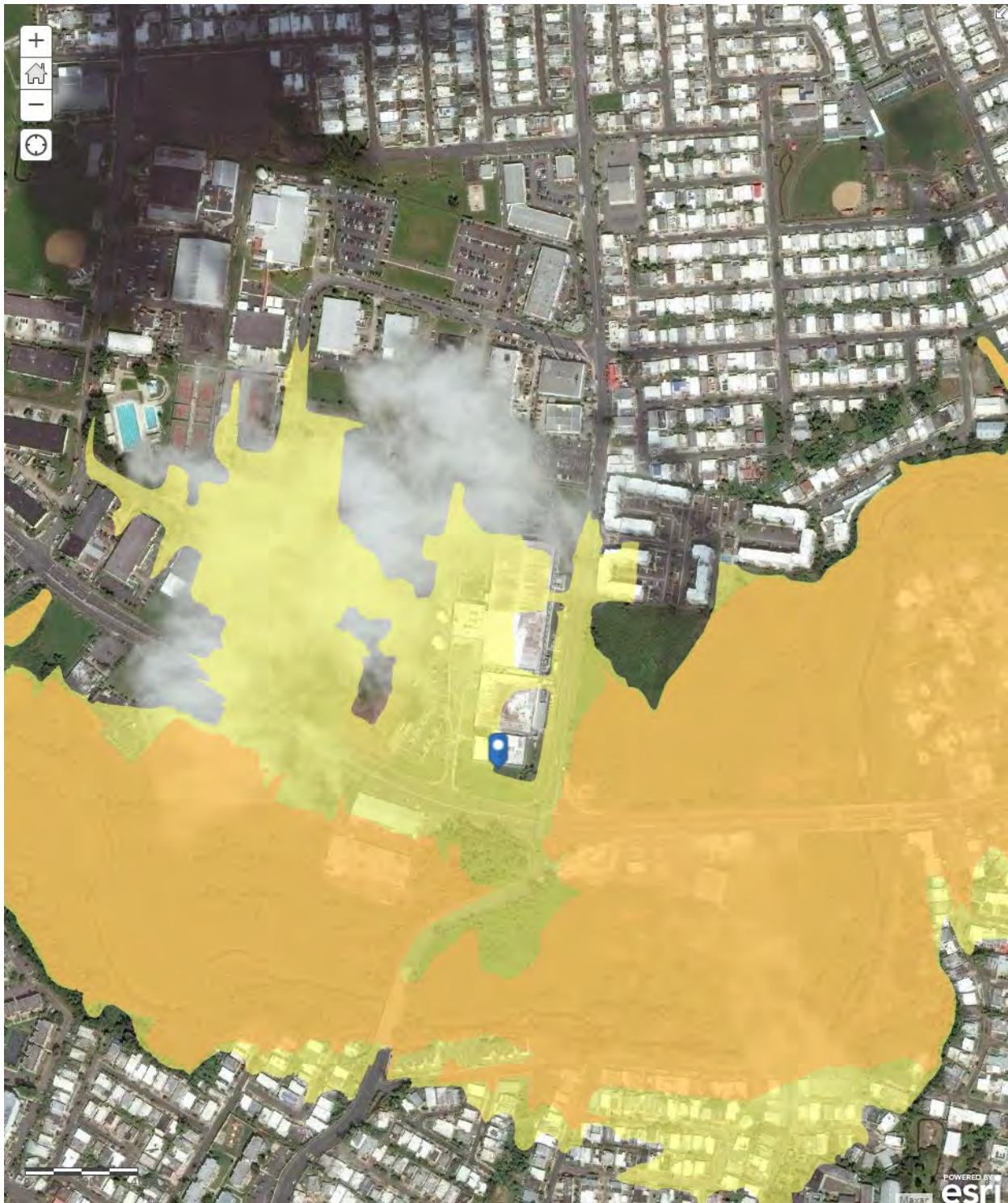
Appendix D: Flood Zone Map

Federal Emergency Management Agency (FEMA) 100 Year Flood Zones and EPA's Region 2 Composite Flood Risk Layer

Facility Name: Aurobindo, Inc. – Caguas



The Facility's boundary is located within the 100-Year Flood Zones FEMA Layer.



The Facility is located within a potential flood risk area based on EPA's Region 2 Composite Flood Risk layer.