US Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
Response and Remediation Branch

Resource Conservation and Recovery Act (RCRA)
Compliance Evaluation Inspection

Facility Name:	Neolpharma, Inc. – Caguas		
EPA ID Number:	PRD090378225		
Date of Inspection:	August 9, 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		
Project ID	CEPD-RCRA-23-0433		
Potential EJ Concern	Yes. 8 EJ Indexes above the 80% USA Percentile. (See Appendix C)		
Potential Flood Prone Area	Yes. The Facility boundaries are within the 100-Year Flood Zone layer (See Appendix D)		
Facility Physical Location: (Municipality, PR, zip code)	99 Jardines St Caguas, PR 00725		
Geographical Coordinates:	18.240619, -66.017865		
Facility Owner:	Neolpharma Inc	787-286-4000	
	99 Jardines St Caguas, PR 00725		
Facility Operator:	Neolpharma Inc	787-286-4000	
	99 Jardines St Caguas, PR 00725		
NAICS:	325412; Pharmaceutical Preparation Manufacturing		
SIC:	2834; Pharmaceutical Preparations		
Area:	~30 acres		
Number Employees:	~200		
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
Vanessa Rodriguez	Neolpharma, Inc.	Manager, EHS	787-286-4159 vanessa.rodriguez@neolpharma.com
Status:	Final		
Record Schedule:	1044(c)		

EPA Inspector Signature/Date	X  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=68001003667785 Date: 2023.08.23 12:23:31 -04'00' Adobe Acrobat version: 2023.003.20284 Carlos Josue Colombani Enforcement Officer
Supervisor Signature/Date	X DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2023.08.23 12:49:31 -04'00' David N. Cuevas Miranda, Ph.D.

CONTENTS

1 INTRODUCTION

On August 9, 2023, a Resource Conservation and Recovery Act (RCRA) Subtitle C Compliance Evaluation Inspection (CEI) was conducted at Neolpharma, Inc. (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 99 Jardines Street, Caguas, Puerto Rico, 00725. See aerial photograph (Figure 1) below for reference.

Figure 1: Neolpharma, Inc. 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 July 27, 2018. Under EPA Policy, LQGs are required to be inspected every five (5) years and thus, an inspection was due in July of 2023. The inspection was unannounced.

2 OPENING CONFERENCE

I met with Ms. Vanessa Rodriguez, Manager of Environmental Health and Safety for the opening conference. I identified myself as an EPA RCRA enforcement officer, told the Facility representative the

purpose of the inspection, and offered 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;
- 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

Neolpharma Group, a Mexican pharmaceutical, has more than 40 (forty) years of experience in the production of prescription and over-the-counter drugs. It is dedicated to research, development, manufacturing, marketing and distribution of pharmaceutical drugs. Neolpharma, Inc. in Caguas, PR consists of state-of-the art technology to produce liquid and solid forms, tablets, capsules and beads. The Facility acquired the plant from Pfizer in January of 2013. In 2017, a 35-million investment was announced that resulted in the expansion of the Facility, additional laboratory equipment for research and development, and created over a hundred jobs.

Neolpharma, Inc. manufactures and packages levothyroxine (Levo-T), a drug used to treat an underactive thyroid (hypothyroidism). The PR plant has easy access to maritime and air transportation, which benefits the transportation for import and export of raw materials as finished products to the United States.

The Facility representative reported that the plant currently employs approximately 200 (two hundred) full-time employees. Neolpharma, Inc. covers an area of about 30 (thirty) acres of land.

2.2 SOLID AND HAZARDOUS WASTE GENERATION

Neolpharma, Inc. generates and stores hazardous and nonhazardous wastes from their research and development (R&D) laboratories, and the manufacturing area and stores them in two (2) central accumulation areas (CAAs), 5 (five) satellite accumulation areas (SAAs), and an assigned area for its universal waste. The CAAs are identified as CAA #1 and CAA #2. The SAAs are located in the Analytical Laboratory #1, the Analytical Laboratory #2, the Raw Material Laboratory #4, the Analytical Laboratory #6, and the Manufacturing area. Hazardous waste is generated daily throughout the Facility and Veolia is their dedicated hauler.

Majority of the hazardous waste 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. Rodriguez accompanied me during the facility walkthrough. The following areas were inspected for compliance:

- Analytical Laboratory #1 SAA;
- Analytical Laboratory #2 SAA;
- Raw Material Laboratory #4 SAA;
- Analytical Laboratory #6 SAA;
- Manufacturing SAA;
- CAA #1;
- CAA #2; and
- Universal Waste Storage Area.

The observations for each area are described below.

3.1 SATELLITE ACCUMULATION AREAS (SAAS)

As mentioned above, the Analytical Laboratories #1, #2, and #6, the Raw Material Laboratory #4, and the Manufacturing SAAs were visited to evaluate compliance with the RCRA regulations.

At the time of the inspection, the Analytical Laboratory #1 SAA had 2 (two) 5-gallon hazardous waste containers of acetonitrile and 2 (two) 5-gallon hazardous waste containers of methanol. One (1) of the containers' storing acetonitrile was found open (See Appendix A, Photograph 1). At that time, laboratory representatives were not adding or removing waste from the container.

The Analytical Laboratory #2 SAA had a 5-gallon hazardous waste container of acetonitrile, a 5-gallon hazardous waste container of methanol and a bucket of waste vials generated from high performance liquid chromatography (HPLC) (See Appendix A, Photograph 2).

At the Raw Material Laboratory #4 SAA, there was a hazardous waste container of pyridine dated August 3, 2023 (See Appendix A, Photograph 3). Under RCRA, a generator must remove the excess from the SAA within three consecutive calendar days to a CAA or to an off-site designated facility. The SAA was also storing a 5-gallon hazardous waste container of acetonitrile and a 5-gallon hazardous waste container of methanol.

The Analytical Laboratory #6 SAA had 3 (three) 5-gallon hazardous waste containers of acetonitrile and 3 (three) 5-gallon hazardous waste containers of methanol.

At the Manufacturing SAA, there was a 55-gallon drum of adhesive solution and contaminated isopropyl alcohol (IPA) (See Appendix A, Photograph 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 AREAS (CAAS)

CAA #1

No hazardous waste was being stored due to a pickup several days prior to the inspection (See Appendix A, Photograph 5).

CAA #2

No hazardous waste was being stored due to a pickup several days prior to the inspection (See Appendix A, Photograph 6).

At the time of the inspection, both CAAs 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 storage drums/containers.

3.3 USED OIL STORAGE

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

3.4 UNIVERSAL WASTE STORAGE AREA

The Facility has a dedicated area solely for universal waste, specifically used fluorescent bulbs and batteries located within the premises in a shipping-type metal container (See Appendix A, Photograph 7). At the time of the inspection, 3 (three) batteries were being stored (See Appendix A, Photograph 8).

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.

Weekly Inspections

CAA #1

The weekly inspection records for CAA #1 were audited on-site from January 2020 through August 2021 since they were readily available. The records from September 2021 through July 2023 were requested electronically given they were not readily available the day of the inspection. Ms. Rodriguez provided weekly inspection records via email on August 18, 2023.

The Facility keeps a binder for the weekly inspection records, and 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.

The following table summarizes the number of weekly inspections by month and calendar year that were not recorded in the checklist.

Calendar Year 2020	Number of Missing Weekly Inspections from Checklist
March	1 week
August	2 weeks

Calendar Year 2021	Number of Missing Weekly Inspections from Checklist
September	1 week
October	1 week
November	1 week
December	4 weeks

Calendar Year 2022	Number of Missing Weekly Inspections from Checklist
January	4 weeks
February	2 weeks
March	4 weeks
April	2 weeks
May	3 weeks
June	4 weeks
July	2 weeks
August	3 weeks
September	3 weeks
October	3 weeks
November	3 weeks
December	3 weeks

As of August 22, 2023, no records have been provided for calendar year 2023.

CAA #2

The Facility was not able to produce any weekly inspection records pertaining the CAA #2.

Contingency Plan

Ms. Rodriguez provided a copy of the Contingency Plan the day of the inspection since it must include specific information and it would require a more in-depth review. I verified that the plan was submitted to local emergency response agencies and that the Facility made arrangements with local responders, that it describes the actions needed to respond to explosions, fires and/or releases of hazardous waste, that it identifies an emergency coordinator alongside a 24/7 emergency telephone number, that it lists emergency equipment with its location and capabilities, and that it includes an evacuation plan. The plan is dated October 2022.

Quick reference guide

The Facility does not have a quick reference guide. For facilities that began operations prior to May 30, 2017, a quick reference guide needs to be prepared and submitted to emergency response agencies as soon as the contingency plan is revised after that date. The Facility's latest contingency plan is from calendar year 2022.

Personnel Training

Annual personnel training was provided on-site for staff associated with the hazardous waste operations of the Facility for calendar year 2022. Participant rosters were provided alongside the training material slides. Ms. Rodriguez stated that RCRA annual refreshers were not conducted for calendar years 2020 and 2021.

The job title and duty documents did not include a written description 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 listed in Appendix B had proper land disposal restriction notification forms based on the shipped waste codes, were dated, and signed by the designated facility, and were processed into EPA's Hazardous Waste Electronic Manifest System (e-Manifest).

In 2020, the Facility shipped approximately 18,531 kilograms of hazardous waste, and 7 kilograms of acute hazardous waste. In 2021, it shipped approximately 12,357 kilograms of hazardous waste, and 16 kilograms of acute hazardous waste. In 2022, the Facility shipped approximately 12,592 kilograms of hazardous waste, and 2 kilograms of acute hazardous waste. So far, in 2023, the Facility has shipped approximately 1,996 kilograms of hazardous waste (from January through April of 2023).

Thus, based on the manifests reviewed for the past three years, and conversations with the Facility representative, 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	7
2020	Non-Acute	18,531
2021	Acute	16
2021	Non-Acute	12,357
2022	Acute	2
2022	Non-Acute	12,592
2023	Non-Acute	1996

Neolpharma, Inc. ships its hazardous waste typically every 2 (two) or 3 (three) months but often sooner given the amount that is 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 28, 2022.

5 CLOSING CONFERENCE

On August 9, 2023, after completion of the walkthrough and onsite document review, I met with Ms. Rodriguez 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 262.15(a)(4): A container holding hazardous waste must be closed at all times during accumulation, except: when adding, removing, or consolidating waste; or when temporary venting of a container is necessary.	At the time of the inspection, the Analytical Laboratory #1 SAA had an open container of acetonitrile. See Appendix A, Photograph 1.
40 CFR § Part 262.15(a)(6)(ii): A generator must remove the excess from the satellite accumulation area within three consecutive calendar days.	At the time of the inspection, the Raw Material Laboratory #4 SAA had a pyridine container dated August 3, 2023. The inspection was conducted on August 9, 2023. See Appendix A, Photograph 3.
40 CFR § Part 262.17(a)(1)(v): At least weekly, the large quantity generator must inspect central accumulation areas.	CAA #1 The following table summarizes weekly inspections that were not recorded in the checklist for calendar years

<table>
<tr><th>REGULATORY, STATUTORY OR PERMIT REFERENCE</th><th>FIELD OBSERVATION</th></tr>
<tr><td></td><td>2020 through 2022. For calendar year 2023, no records were provided.

<table>
<tr><th>Calendar Year 2020</th><th>Number of Missing Weekly Inspections from Checklist</th></tr>
<tr><td>March</td><td>1 week</td></tr>
<tr><td>August</td><td>2 weeks</td></tr>
</table>

<table>
<tr><th>Calendar Year 2021</th><th>Number of Missing Weekly Inspections from Checklist</th></tr>
<tr><td>September</td><td>1 week</td></tr>
<tr><td>October</td><td>1 week</td></tr>
<tr><td>November</td><td>1 week</td></tr>
<tr><td>December</td><td>4 weeks</td></tr>
</table>

<table>
<tr><th>Calendar Year 2022</th><th>Number of Missing Weekly Inspections from Checklist</th></tr>
<tr><td>January</td><td>4 weeks</td></tr>
<tr><td>February</td><td>2 weeks</td></tr>
<tr><td>March</td><td>4 weeks</td></tr>
<tr><td>April</td><td>2 weeks</td></tr>
<tr><td>May</td><td>3 weeks</td></tr>
<tr><td>June</td><td>4 weeks</td></tr>
<tr><td>July</td><td>2 weeks</td></tr>
<tr><td>August</td><td>3 weeks</td></tr>
<tr><td>September</td><td>3 weeks</td></tr>
<tr><td>October</td><td>3 weeks</td></tr>
<tr><td>November</td><td>3 weeks</td></tr>
<tr><td>December</td><td>3 weeks</td></tr>
</table>

CAA #2

The Facility was not able to produce weekly inspections for the past 3 (three) years.</td></tr>
</table>

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 was not able to produce a Quick Reference Guide.
40 CFR § Part 262.17(a)(7)(iii): Facility personnel must take part in an annual review of the initial training.	The Facility was not able to produce RCRA personnel training records for calendar year 2020 and 2021.
40 CFR § Part 262.17(a)(7)(iv)(C): The LQG must maintain the following documents and records at the facility: a written description of the type and amount of both introductory and continuing training that will be given to each person.	The job title and duty documents provided for "Environmental Support Services Technician", "Sr. Pharmaceutical Services Operator", "Quality Operations Clerk", and "Environmental, Health and Safety Manager" did not include a written description of the type and amount of both introductory and continuing training that needs to be given to each person in and/or filling the position.

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

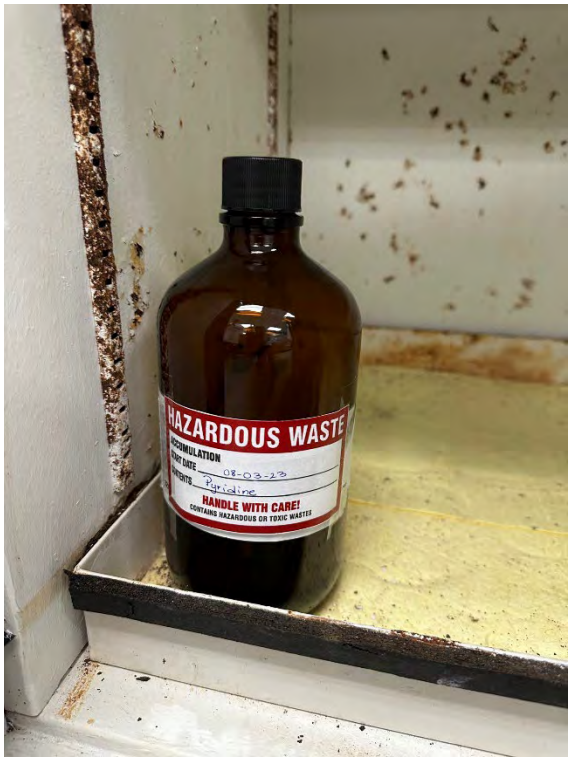
8 APPENDICES

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

Appendix A: Inspection Photos

Photograph 1: Open container of acetonitrile at the Analytical Laboratory #1 SAA.

Photograph 2: Waste vials of HPLC at the Analytical Laboratory #2 SAA.



Photograph 3: Container of pyridine dated August 3, 2023 at the Raw Material Laboratory #4 SAA.

Photograph 4: 55-gallon drum of adhesive and contaminated IPA at the Manufacturing SAA.

Photograph 5: Overview of CAA #1 with no hazardous waste.

Photograph 6: Overview of CAA #2 with no hazardous waste.

Photograph 7: UW Storage Area metal container.

Photograph 8: UW batteries at the UW Storage Area.

Appendix B: Hazardous Waste Manifests

Manifest Date	Waste (kg)	Manifest Tracking Number
4/27/2023	363	002066173VES
4/27/2023	1,633	002066173VES
12/30/2022	601	002066182VES
12/30/2022	11	002066184VES
12/30/2022	1	002066184VES
12/30/2022	7	002066184VES
12/30/2022	20	002066184VES
12/30/2022	2,177	002066182VES
12/30/2022	95	002066183VES
12/30/2022	1	002066184VES
12/30/2022	45	002066184VES
12/30/2022	318	002066183VES
12/30/2022	1	002066184VES
12/30/2022	3	002066184VES
12/30/2022	2	002066184VES
12/30/2022	5	002066184VES
9/13/2022	352	002064276VES
9/13/2022	20	002064276VES
9/13/2022	5	002064276VES
9/13/2022	39	002064276VES
9/13/2022	363	002064275VES
9/13/2022	50	002064276VES
9/13/2022	5	002064276VES
9/13/2022	57	002064276VES
9/13/2022	5	002064276VES
9/13/2022	5	002064276VES
9/13/2022	5	002064276VES
9/13/2022	7	002064276VES
9/12/2022	392	002067048VES
9/12/2022	1,814	002067048VES
6/14/2022	54	002069862VES
6/14/2022	18	002069863VES
6/14/2022	11	002069863VES
6/14/2022	57	002069863VES
6/14/2022	2	002069863VES
6/14/2022	2	002069863VES
6/14/2022	3	002069863VES

6/14/2022	2	002069863VES
6/14/2022	2,722	002069862VES
6/14/2022	84	002069863VES
6/14/2022	2	002069863VES
6/14/2022	26	002069863VES
6/14/2022	2	002069863VES
6/14/2022	2	002069863VES
6/14/2022	18	002069863VES
6/14/2022	2	002069863VES
2/25/2022	803	002064131VES
2/25/2022	6	002064115VES
2/25/2022	9	002064115VES
2/25/2022	4	002064115VES
2/25/2022	11	002064115VES
2/25/2022	5	002064115VES
2/25/2022	2,177	002064131VES
2/25/2022	27	002064115VES
2/25/2022	1	002064115VES
2/25/2022	50	002064115VES
2/25/2022	70	002064115VES
2/25/2022	2	002064115VES
2/25/2022	5	002064115VES
2/25/2022	5	002064115VES
2/25/2022	2	002064115VES
2/25/2022	2	002064115VES
2/25/2022	1	002064115VES
11/29/2021	363	002069503VES
11/29/2021	68	002069504VES
11/29/2021	30	002069505VES
11/29/2021	2	002069505VES
11/29/2021	1	002069505VES
11/29/2021	13	002069505VES
11/29/2021	2,540	002069503VES
11/29/2021	66	002069505VES
11/29/2021	2	002069505VES
11/29/2021	12	002069505VES
11/29/2021	59	002069505VES
11/29/2021	15	002069505VES
11/29/2021	1	002069505VES

11/29/2021	1	002069505VES
11/29/2021	1	002069505VES
11/29/2021	2	002069505VES
11/29/2021	1	002069505VES
8/23/2021	441	001659979VES
8/23/2021	143	001659978VES
8/23/2021	20	001659978VES
8/23/2021	5	001659978VES
8/23/2021	5	001659978VES
8/23/2021	79	001659978VES
8/23/2021	1,814	001659979VES
8/23/2021	73	001659978VES
8/23/2021	29	001659978VES
8/23/2021	20	001659978VES
8/23/2021	18	001659978VES
8/23/2021	41	001659978VES
8/23/2021	5	001659978VES
8/23/2021	5	001659978VES
8/23/2021	5	001659978VES
8/23/2021	20	001659978VES
8/23/2021	5	001659978VES
8/23/2021	18	001659978VES
6/7/2021	220	001656993VES
6/7/2021	132	001656994VES
6/7/2021	5	001656994VES
6/7/2021	1	001656994VES
6/7/2021	14	001656994VES
6/7/2021	2,354	001656993VES
6/7/2021	74	001656995VES
6/7/2021	3	001656994VES
6/7/2021	3	001656994VES
6/7/2021	21	001656994VES
6/7/2021	1	001656994VES
6/7/2021	15	001656994VES
6/7/2021	41	001656995VES
6/7/2021	10	001656994VES
6/7/2021	2	001656994VES
6/7/2021	1	001656994VES
6/7/2021	1	001656995VES

3/12/2021	771	001849102VES
3/12/2021	14	001849101VES
3/12/2021	11	001849103VES
3/12/2021	57	001849104VES
3/12/2021	5	001849101VES
3/12/2021	4	001849101VES
3/12/2021	5	001849101VES
3/12/2021	10	001849101VES
3/12/2021	2,359	001849102VES
3/12/2021	122	001849101VES
3/12/2021	5	001849101VES
3/12/2021	54	001849101VES
3/12/2021	4	001849101VES
3/12/2021	109	001849101VES
3/12/2021	7	001849101VES
3/12/2021	5	001849101VES
3/12/2021	5	001849101VES
3/12/2021	8	001849101VES
3/12/2021	1	001849101VES
12/15/2020	567	001513441VES
12/15/2020	8	001513440VES
12/15/2020	19	001513440VES
12/15/2020	1	001513440VES
12/15/2020	1	001513440VES
12/15/2020	2,173	001513441VES
12/15/2020	66	001513442VES
12/15/2020	1	001513440VES
12/15/2020	8	001513440VES
12/15/2020	19	001513440VES
12/15/2020	61	001513442VES
12/15/2020	1	001513442VES
12/15/2020	1	001513442VES
9/28/2020	436	001659877VES
9/28/2020	3	001659875VES
9/28/2020	25	001659875VES
9/28/2020	15	001659875VES
9/28/2020	1	001659875VES
9/28/2020	3,280	001659877VES
9/28/2020	125	001659876VES

9/28/2020	20	001659875VES
9/28/2020	1	001659875VES
9/28/2020	2	001659875VES
9/28/2020	234	001659876VES
9/28/2020	3	001659876VES
9/28/2020	13	001659875VES
9/28/2020	2	001659875VES
9/28/2020	15	001659876VES
7/9/2020	57	001849949VES
7/9/2020	2	001849951VES
7/9/2020	1	001849951VES
7/9/2020	1	001849951VES
7/9/2020	9	001849951VES
7/9/2020	3,050	001849949VES
7/9/2020	147	001849950VES
7/9/2020	4	001849951VES
7/9/2020	86	001849952VES
7/9/2020	9	001849951VES
7/9/2020	176	001849950VES
7/9/2020	8	001849951VES
7/9/2020	1	001849951VES
7/9/2020	1	001849951VES
7/9/2020	9	001849951VES
7/9/2020	4	001849950VES
4/27/2020	760	001513219VES
4/27/2020	342	001513221VES
4/27/2020	20	001513221VES
4/27/2020	3,084	001513219VES
4/27/2020	181	001513220VES
4/27/2020	20	001513221VES
4/27/2020	54	001513221VES
4/27/2020	181	001513220VES
4/27/2020	20	001513221VES
4/27/2020	5	001513221VES
4/27/2020	5	001513221VES
4/27/2020	5	001513221VES
4/27/2020	7	001513220VES
4/27/2020	5	001513221VES
2/17/2020	71	001513329VES

2/17/2020	90	001513330VES
2/17/2020	3	001513331VES
2/17/2020	8	001513331VES
2/17/2020	19	001513331VES
2/17/2020	7	001513331VES
2/17/2020	2	001513331VES
2/17/2020	2,711	001513329VES
2/17/2020	46	001513331VES
2/17/2020	2	001513331VES
2/17/2020	173	001513331VES
2/17/2020	10	001513329VES
2/17/2020	22	001513331VES
2/17/2020	2	001513329VES
2/17/2020	10	001513331VES
2/17/2020	7	001513329VES
2/17/2020	1	001513331VES

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 18.240619,-66.017865
Population: 17,099
Area in square miles: 3.14

LANGUAGES SPOKEN AT HOME

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

COMMUNITY INFORMATION

- Low income: 72 percent
- People of color: 98 percent
- Less than high school education: 13 percent
- Limited English households: 68 percent
- Unemployment: 21 percent
- Persons with disabilities: 32 percent
- Male: 43 percent
- Female: 57 percent
- 0 years — Average life expectancy
- $14,028 — Per capita income
- Number of households: 7,019
- Owner occupied: 60 percent

BREAKDOWN BY RACE

- White: 56%
- Black: 9%
- Asian: 0%
- Hispanic: 97%
- American Indian: 0%
- Hawaiian/Pacific Islander: 0%
- Other race: 22%
- Two or more races: 13%

BREAKDOWN BY AGE

From Ages 1 to 4	4%
From Ages 1 to 18	17%
From Ages 18 and up	83%
From Ages 65 and up	23%

LIMITED ENGLISH SPEAKING BREAKDOWN

Speak Spanish	100%
Speak Other Indo-European Languages	0%
Speak Asian-Pacific Island Languages	0%
Speak Other Languages	0%

Notes: Numbers may not sum to totals due to rounding. Hispanic popultion 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.

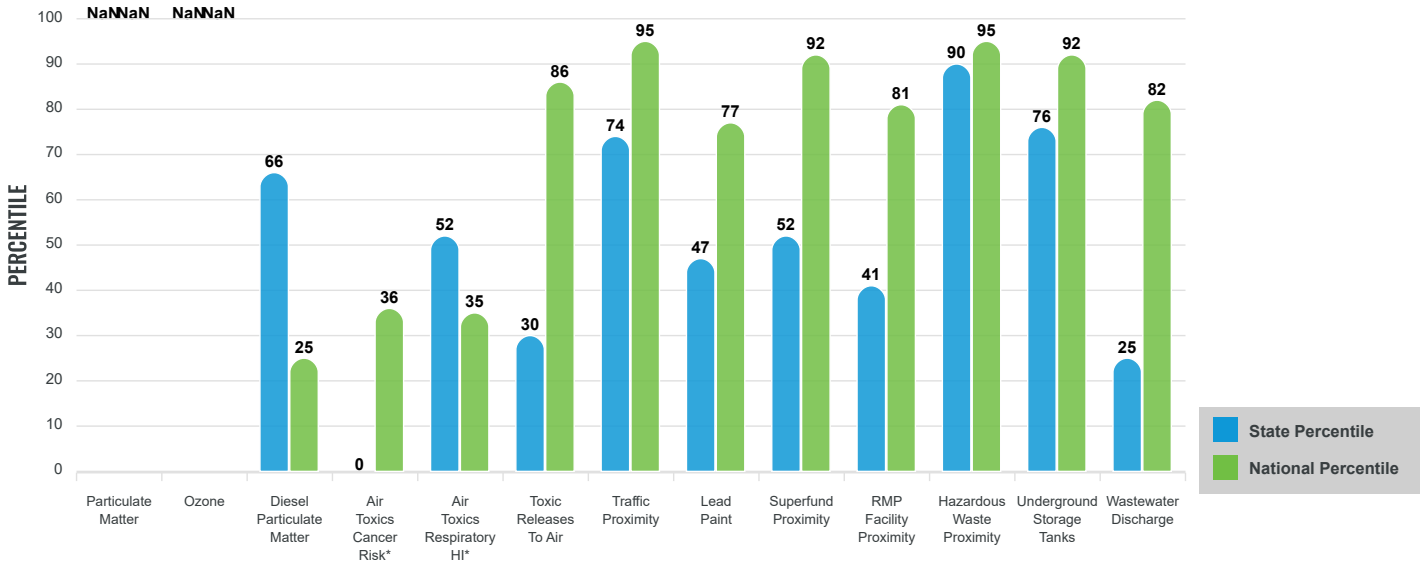
Environmental Justice & Supplemental Indexes

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.

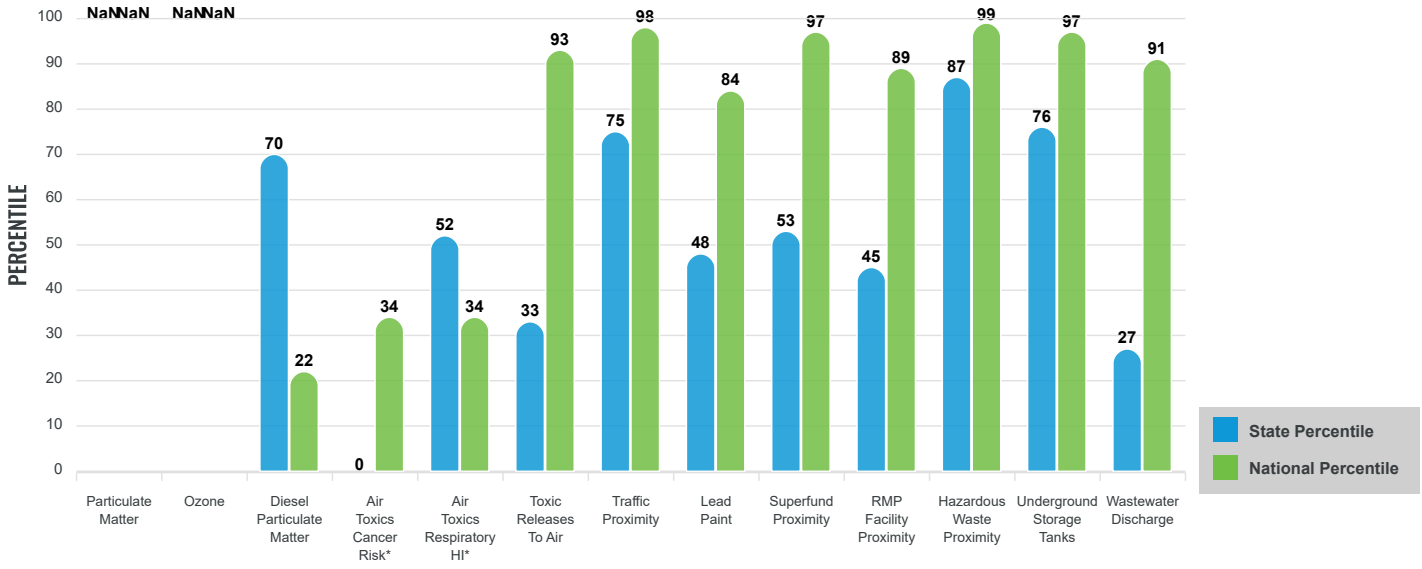
EJ INDEXES FOR THE SELECTED LOCATION



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 18.240619,-66.017865

EJScreen Environmental and Socioeconomic Indicators Data

SELECTED VARIABLES	VALUE	STATE AVERAGE	PERCENTILE IN STATE	USA AVERAGE	PERCENTILE IN USA
POLLUTION AND SOURCES					
Particulate Matter (µg/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 (µg/m^3)	0.0583	0.0667	64	0.261	5
Air Toxics Cancer Risk* (lifetime risk per million)	20	23	0	28	3
Air Toxics Respiratory HI*	0.2	0.19	17	0.31	4
Toxic Releases to Air	430	4,300	27	4,600	44
Traffic Proximity (daily traffic count/distance to road)	250	180	76	210	80
Lead Paint (% Pre-1960 Housing)	0.11	0.16	56	0.3	37
Superfund Proximity (site count/km distance)	0.084	0.15	52	0.13	60
RMP Facility Proximity (facility count/km distance)	0.14	0.47	40	0.43	41
Hazardous Waste Proximity (facility count/km distance)	1.9	0.76	89	1.9	73
Underground Storage Tanks (count/km^2)	3.8	1.7	83	3.9	71
Wastewater Discharge (toxicity-weighted concentration/m distance)	0.00083	2.3	31	22	47
SOCIOECONOMIC INDICATORS					
Demographic Index	85%	83%	42	35%	97
Supplemental Demographic Index	43%	43%	43	14%	99
People of Color	98%	96%	19	39%	95
Low Income	72%	70%	43	31%	94
Unemployment Rate	21%	15%	72	6%	96
Limited English Speaking Households	68%	67%	45	5%	99
Less Than High School Education	13%	21%	30	12%	68
Under Age 5	4%	4%	67	6%	46
Over Age 64	23%	22%	58	17%	77
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 7
Air Pollution 2
Brownfields 0
Toxic Release Inventory 1

Other community features within defined area:

Schools 6
Hospitals 1
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 18.240619,-66.017865

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	29.7%	21.6%	86	13.4%	98

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	21%	32%	31	14%	76
Lack of Health Insurance	7%	7%	60	9%	52
Housing Burden	Yes	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

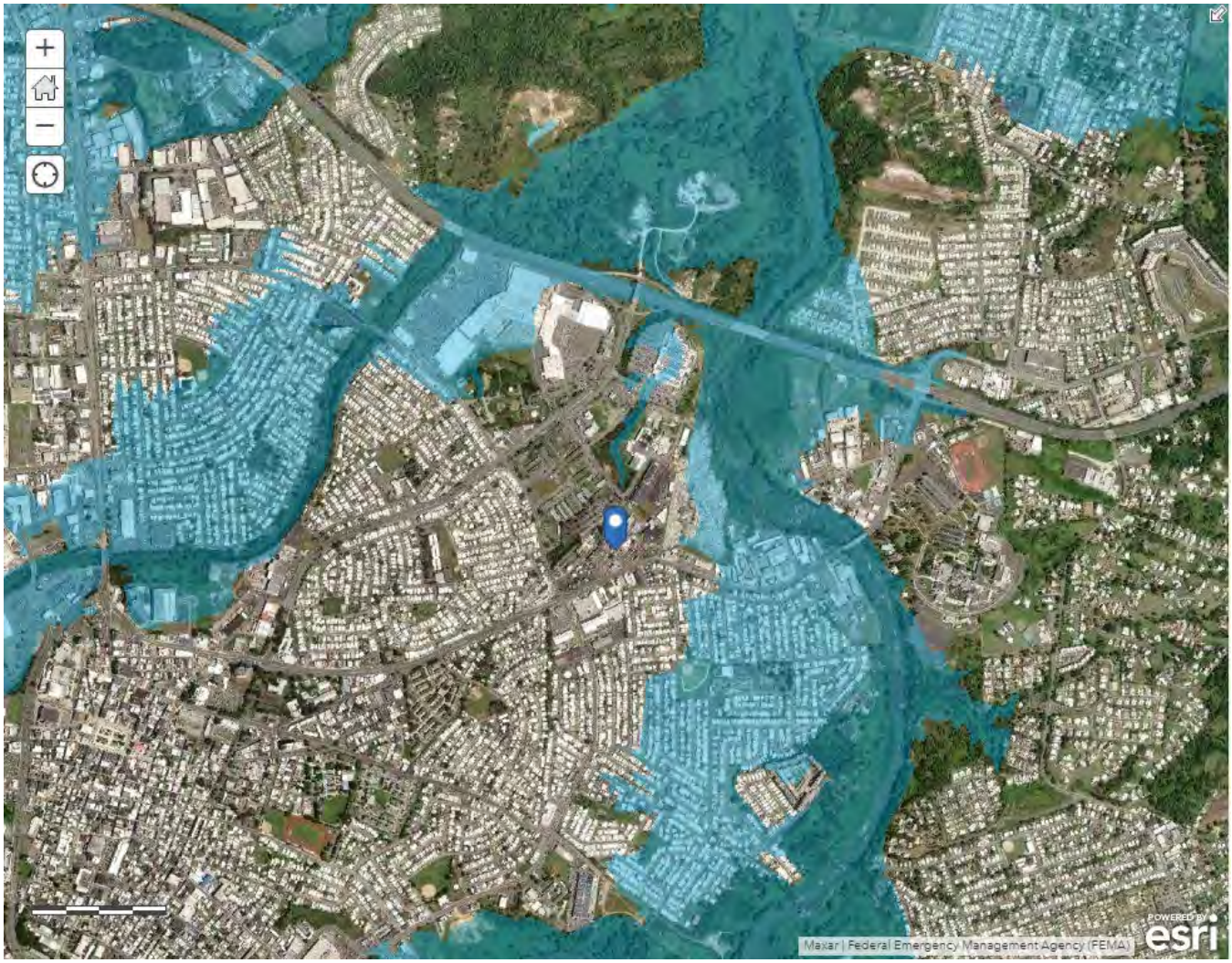
Footnotes

Report for 1 mile Ring Centered at 18.240619,-66.017865

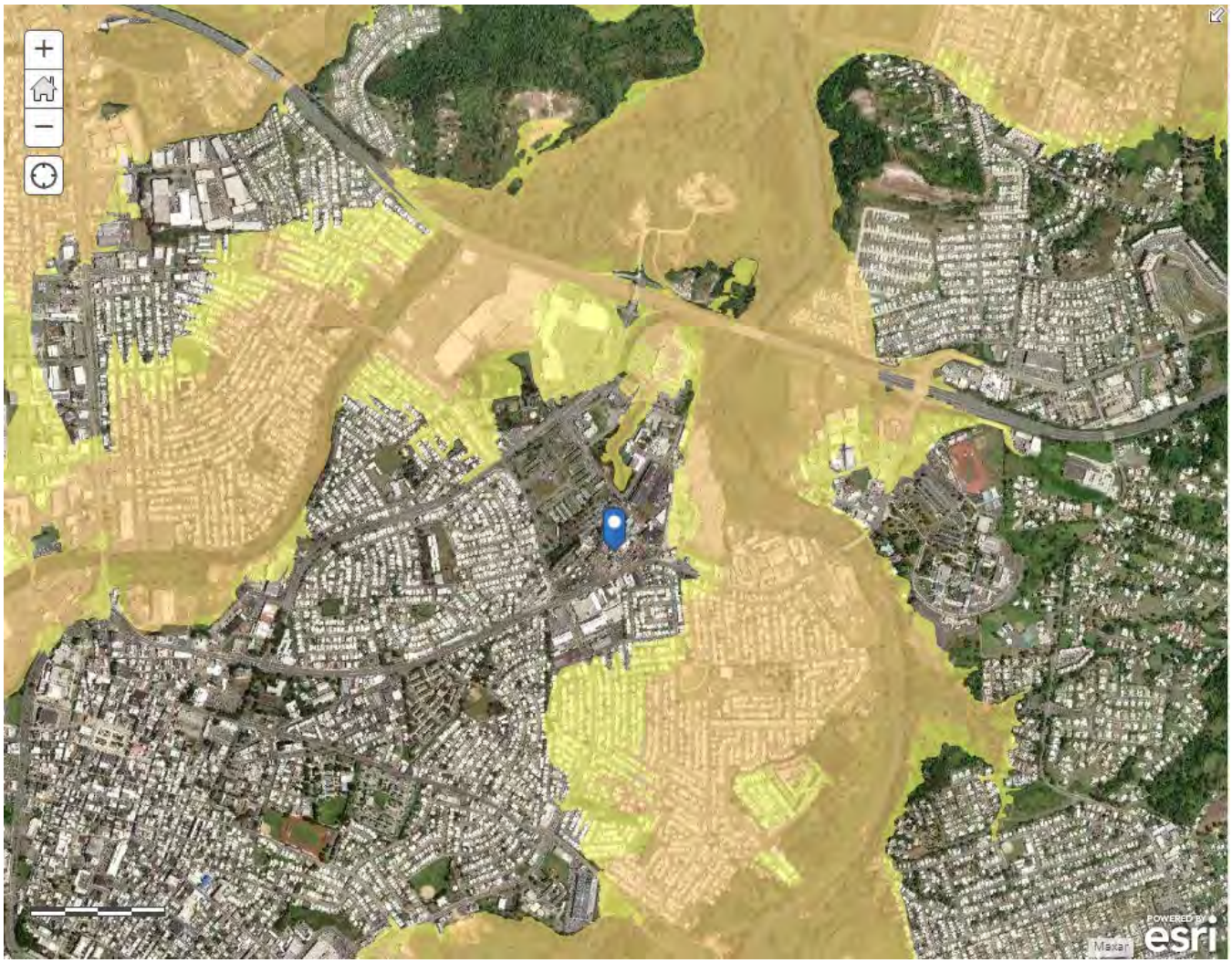
Appendix D: Flood Zone Map

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

Facility Name: Neolpharma, Inc. – Caguas



The Facility boundaries are within the 100-Year Flood Zones FEMA Layer.



The Facility boundaries are within a high composite potential risk area based on EPA's Region 2 Composite Flood Risk layer.