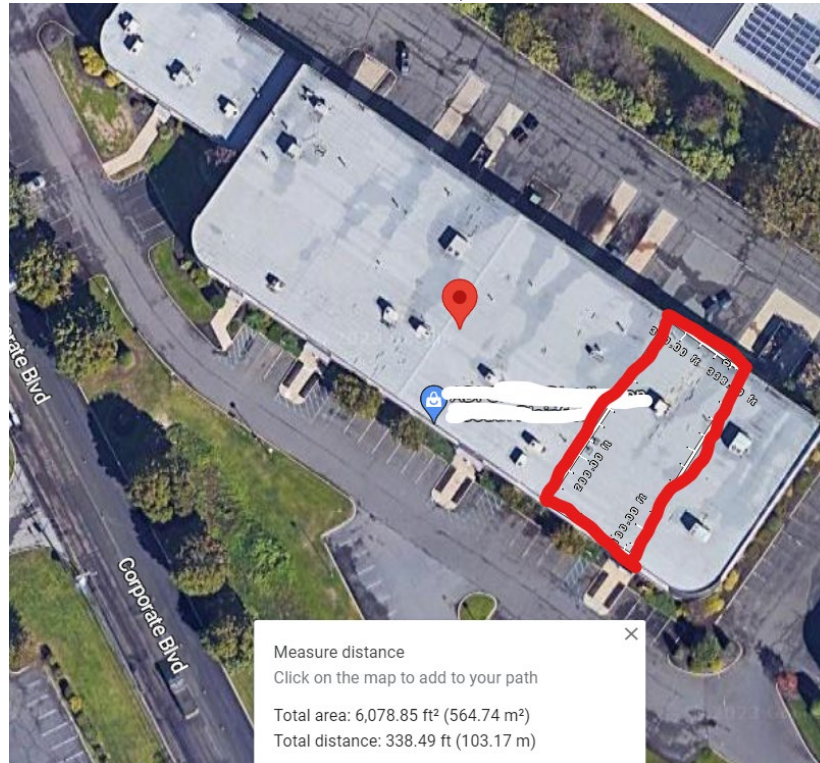


Off-Site Compliance Monitoring Report
Sciencetech Laboratories Inc.
107 G Corporate Boulevard, South Plainfield, N.J.
March 15, 2023



Written by:

X James
Sullivan

Digitally signed by James
Sullivan
Date: 2023.03.28
07:11:56 -04'00'

Enforcement Officer
ECAD-CAPSB-CAS USEPA R2

Approved by:

X KATHLEEN
MALONE-
BOGUSKY

Digitally signed by KATHLEEN
MALONE-BOGUSKY
Date: 2023.03.28 09:22:12
-04'00'

Chief - Compliance Assurance Section
ECAD-CAPSB-CAS USEPA R2

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COMPLIANCE EVALUATION INSPECTION REPORT

U.S. Environmental Protection Agency, Region 2
Enforcement and Compliance Assurance Division
290 Broadway, 21st floor
New York, New York 10007-1866

Locational Information

Facility Name: Scientech Laboratories Inc.
Facility Address: 107 G Corporate Boulevard, South Plainfield, New Jersey 07080
Latitude & Longitude: 40.549224; -74.42143

ICIS & other Program ID Codes as appropriate

FRS: 110069396335
Program: NJN986650869

Sector Information

Federal Facility: No
SIC: 8734 - Testing Laboratories
NAICS: 54138 - Testing Laboratories and Services

Environmental Sensitivity Information

Potential Flood-Prone Area: No (See Appendix B: FEMA Flood Map)
Sole Source Aquifer: No (See Appendix C: Sole Source Aquifer Map)
Potential EJ Concerns: Yes (See Appendix D: EJ SCREEN)

Inspection Information

Date of Inspection: March 15, 2023
Inspector(s): Jim Sullivan
Inspector(s) Organization Code(s): 2-ECAD-CAPSB

Facility Representative(s):

Name	Title	Phone	Email
Bina B. Clark	Chief Executive Officer	(908) 561-6330	bbclark@scientech-labs.com

Corrections/Updates for EPA Databases: The company will be filing for a new permanent EPA ID number that begins with NJD, rather than the temporary NJR number that they have been using.

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1. INTRODUCTION

On March 15, 2023, the Region 2 Office of the Environmental Protection Agency (EPA) conducted an off-site compliance monitoring (OfCM) activity of the Sciencetech Laboratories Inc. at 107 G Corporate Boulevard in South Plainfield, New Jersey. The purpose of this OfCM activity was to evaluate the facility's compliance with the Resource Conservation and Recovery Act (RCRA) requirements for hazardous waste management.

Per their website, the mission of Sciencetech Laboratories Inc. (Sciencetech) is to be the complete solution for the biopharmaceutical industry's analytical testing and research and development needs. The company offers the following services:

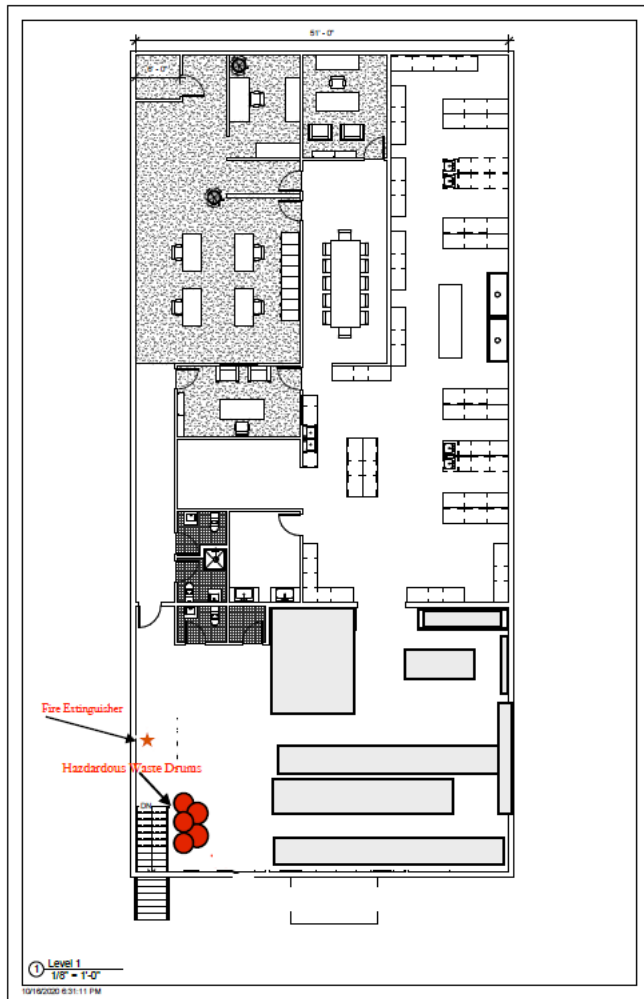
- Analytical Testing, including method development & validation, deformation, extractables & leachables, impurities testing, unknown & contamination identification, failure analysis cleaning & process validation, batch release testing, and materials identification testing;
- Stability Studies & Testing, including cGMP (current Good Manufacturing Practice requirements) stability study protocols, protocol design and management plan, stability indicating method development and validation, API stability testing, customized reporting, stability chambers back-up, forced degradation testing, real-time stability testing, accelerated stability testing and ICH (International Council on Harmonization) conditions;
- Consulting & Lab Services, including regulatory compliance consulting and elemental impurities consulting; and
- Formulation Testing, including pharmaceutical formulation & process development, pre-formulation services, GMP clinical trial manufacturing, cleaning & process validation, full program support, and topical product development.

Sciencetech provides services to the pharmaceutical, wellness, beauty care, personal care, cosmetics, nutraceuticals, cannabis derived products, chemical, active pharmaceutical ingredients (API) manufacturing and consumer products industries.

On January 17, 2023, I reached out to Sciencetech via email to acquire a point of contact and to inform any company representative that their facility had been selected for an OfCM activity. On January 18th, I received an e-mail from Bina Clark, Sciencetech's Chief Executive Officer, informing me that she would be the lead for the company in responding to my requests. At that time, Sciencetech had not been inspected for hazardous waste compliance by either EPA or the New Jersey Department of Environmental Protection (NJDEP). However, on February 22nd, the NJDEP informed me that they had an inspector on-site who was conducting a RCRA inspection. This inspection was taking place while I was still requesting information from Sciencetech. Thus, I did not pursue additional information related to any violations that were cited by NJDEP per their inspection.

2. FACILITY TOUR

A facility tour was not taken. This was a desktop audit conducted via phone, email, and shared files. The site map below was supplied that highlights the areas where waste is generated or stored.



None of the photos in Appendix A contain proprietary/confidential business information.

3. RECORD REVIEW

To begin the OfCM activity, I requested copies of the last three (3) years of hazardous waste manifests (i.e., the signed treatment, storage, and disposal facility (TSDF) copies) to determine whether the generator status of the facility is either a large, small, or very small quantity generator. Based on a review of those manifests, Sciencetech is a small quantity generator (SQG) of hazardous waste. A review of the data in the E-Manifest database indicated that those manifests associated with shipments to Cycle Chem of Elizabeth, New Jersey were not in the

system. That issue was referred to NJDEP for follow up with Cycle Chem.

Sciencetech typically ships two drums of hazardous waste off each quarter. The waste is high-performance liquid chromatography (HPLC) liquids and is represented on hazardous waste manifests as D001/ F003 methanol and acetonitrile waste flammable liquids. If there is toluene in the mixture, then the F005 waste code is added. The manifest review identified one period of accumulation that exceeded 180 days. That accumulation period was from November 19, 2021, to June 16, 2022 (209-days). Vision Environmental of Somerset New Jersey is Sciencetech's consultant and assists with the hazardous waste shipments. Each year the destination TSDF changes. In 2020, the waste went to Giant Resource & Recovery of Sumter, South Carolina and Tradebe of East Chicago, Indiana. In 2021, hazardous waste was shipped to Cycle Chem of Elizabeth, New Jersey. In 2022, hazardous waste was shipped to Norlite of Cohoes, New York.

Sciencetech asserts that the most hazardous waste they would ever accumulate on-site at one time is three 55-gallon drums. That accumulation limit ensures that the facility will never come close to the 6,000-kilograms of hazardous waste accumulation limit that would move Sciencetech into the large quantity generator category. At the time of the OfCM activity, Sciencetech was filling three 55-gallon drums of hazardous waste. The drums were labeled as waste chloroform, controlled substance solution and mobile phase waste, but were without the words "Hazardous Waste" and an indication of the hazards associated with the containers' contents (See, Photographs #1 - #4).

The company's emergency coordinators are Marjorie Mawuntu and Anitha Velusamy. The company trains its employees on emergency response procedures and proper waste handling via a series of standard operating procedures entitled "Laboratory Safety," "Handling Chemicals and Reagents" and "Emergency Response in Handling Hazardous/Non-Hazardous Waste." The SOPs discuss how the company will conduct weekly inspections of the waste storage area, protect against storage of incompatible chemicals in proximity to each other, and provide a map of all fire extinguisher locations, pull boxes and eyewash stations. Fire extinguishers are inspected by the Fire Marshal for the Borough of South Plainfield and BFPE International Fire Protection.

The company does not manage universal waste as its landlord takes care of all spent lamps and any aerosol spray cans that are received for testing from the clients are not considered waste by Sciencetech and are taken back by the clients. Used oil is not generated at the site.

The facility has not had an emergency incident in the past three years involving hazardous waste or universal waste that required an emergency response.

On March 15, 2023, I conducted a close-out meeting via phone and informed Ms. Clark of my findings based on the information that had been supplied by Sciencetech. I also provided compliance assistance in response to Ms. Clark's questions.

4. REGULATORY CONCERNS

Based on a review of records related to this OfCM activity, the following regulatory concerns

were noted:

REGULATORY, STATUTORY OR PERMIT REFERENCE	FIELD OBSERVATION
Pursuant to 40 C.F.R. § 262.16(b)(6)(i)(A & B) and N.J.A.C. 7:26G, a SQG must mark or label its containers with the following: (A) The words “Hazardous Waste”; and (B) 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).	At the time of this OfCM activity, there were three (3) 55-gallon containers that were without the words “Hazardous Waste” and an indication of the hazards associated with the containers’ contents.
Pursuant to 40 C.F.R. § 262.16(b) and N.J.A.C. 7:26G, a SQG must not accumulate hazardous waste on site for more than 180 days.	At the time of this OfCM activity, there was a gap of 207 days found between Manifest Number 023453064JJK shipped off-site on June 16, 2022, and Manifest Numbers 016420089FLE and 016420090FLE shipped off-site on November 19, 2021.
Pursuant to 40 C.F.R. § 262.16(b)(8)(vi)(A) and N.J.A.C. 7:26G, a SQG must attempt to make arrangements with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals, taking into account the types and quantities of hazardous wastes handled at the facility. Arrangements may be made with the local emergency planning committee, if it is determined to be the appropriate organization with which to make arrangements.	At the time of this OfCM activity, Sciencetech had not made arrangements with local emergency agencies.

5. SCREENING CONCERNS

There were no concerns identified based on screening for other environmental, safety and health aspects outside the scope of this inspection via the U.S. EPA Region 2 Inspector’s Multi-Media Checklist.

6. ENVIRONMENTAL ASSISTANCE

Based on the records reviewed during the OfCM activity, 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:

- EPA’s Small Business Resources Information Sheet, which contains relevant resources to help any facility understand and comply with federal and state environmental laws as well as find cost-effective ways to comply through pollution prevention techniques and innovative technologies (<https://www.epa.gov/compliance/small-business-resources-information-sheet>); and
- Hazardous Waste Portal, which catalogs over 800 hazardous waste compliance resources, including guidebooks, fact sheets, reports, checklists, web sites, contacts, and regulations. Various features are available to assist users in finding the best guidance materials and answers to specific questions. The Hazardous Waste Portal can be found at: <https://www.hazwasteportal.org/>

APPENDICES:

A: Photographs

B: FEMA Flood Map

C: Sole Source Aquifer Map

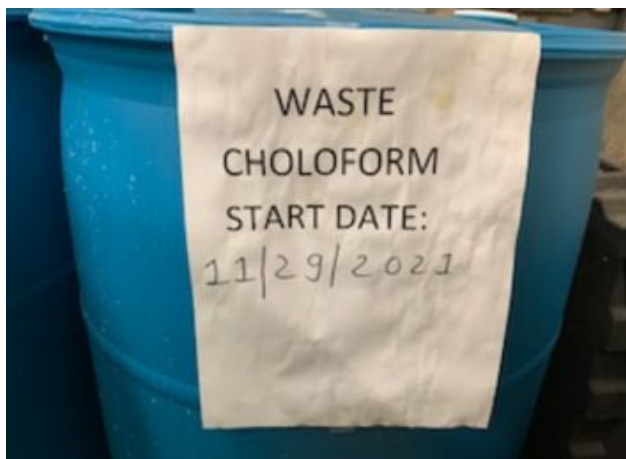
D: EJ Screen

Appendix A: INSPECTION PHOTOS

Photograph #1 – Central Hazardous waste accumulation area



Photograph #2 – Drum without hazardous waste label



Photograph #3 – Drum without hazardous waste label



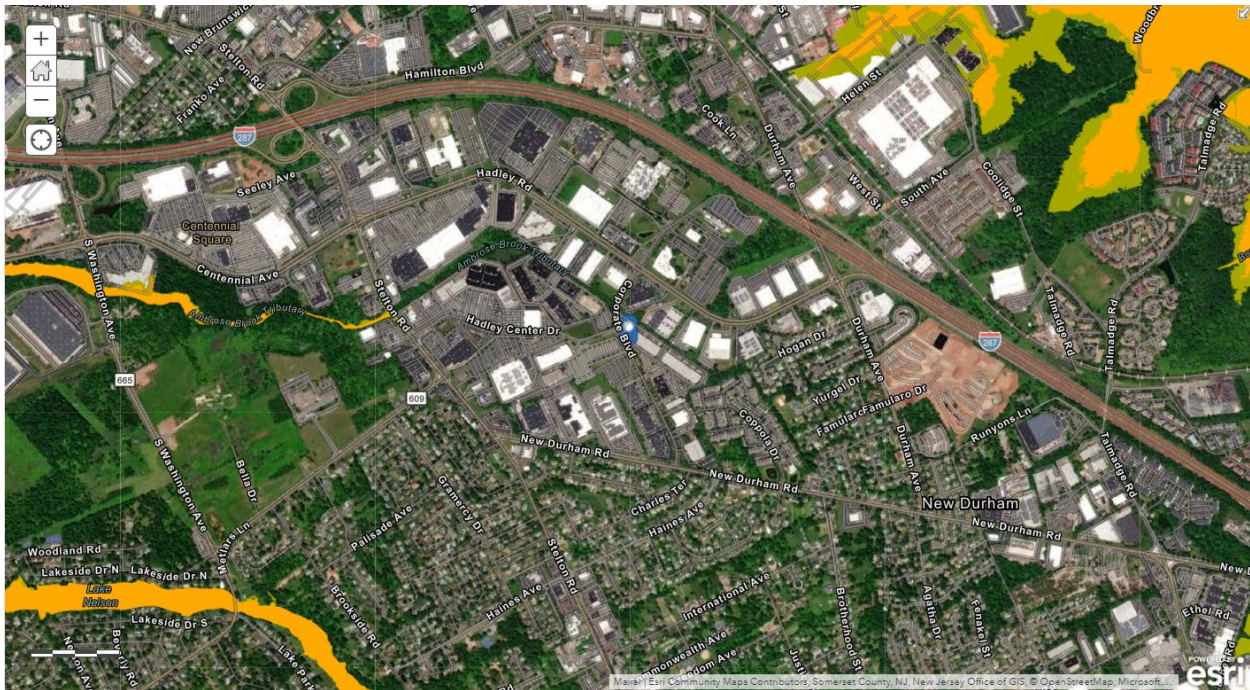
Photograph #4 – Drum without hazardous waste label



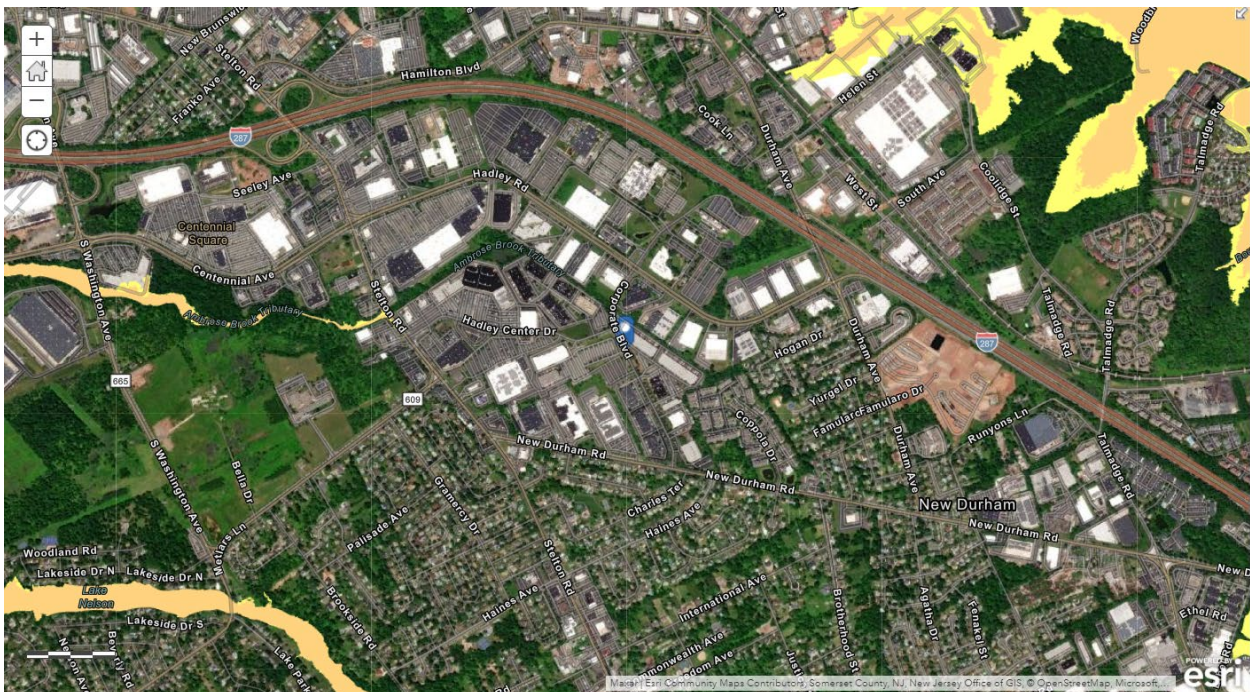
Photograph #5 – Satellite accumulation area. This photo was taken after a visit by NJDEP



**Appendix B: Federal Emergency Management Agency (FEMA) 100 Year Flood Zone and
EPA's Region 2 Composite Flood Risk Layer**
Facility Name: Sciencetech Laboratories Inc.



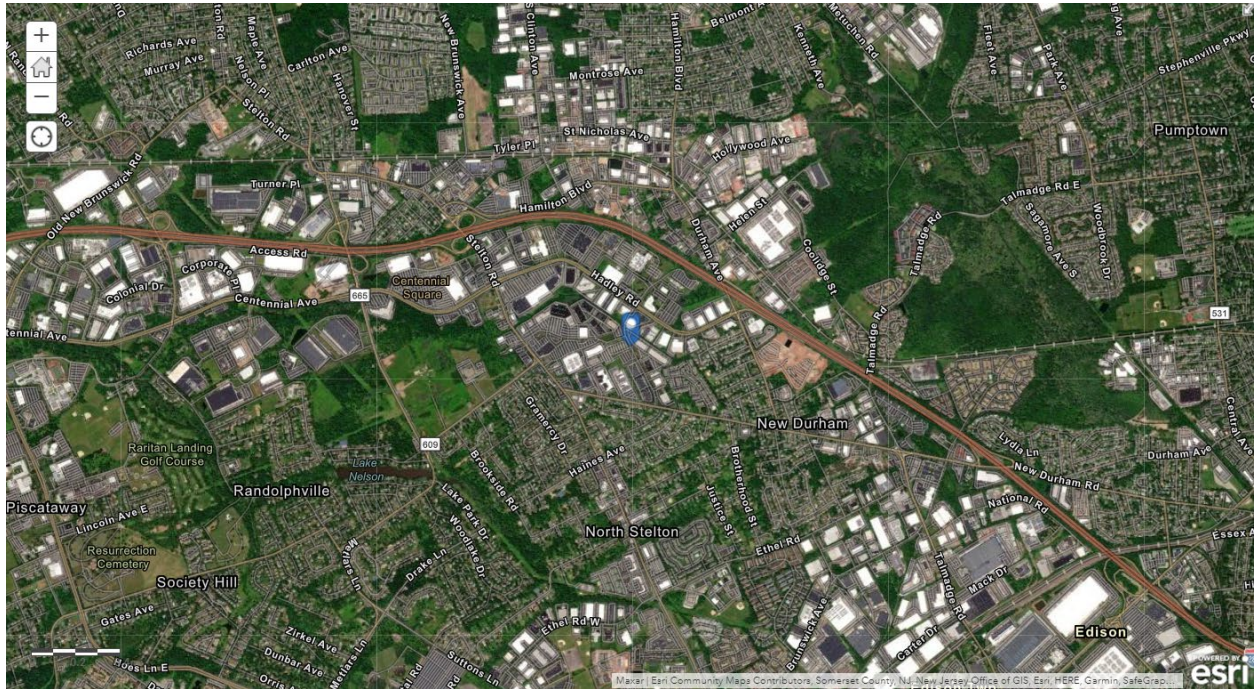
The facility is not located within a FEMA 100-year flood zone area.



The facility is not located within the EPA's Region 2 Composite Flood Risk potential risk area.

Appendix C: Sole Source Aquifer Map

Facility Name: Sciencetech Laboratories Inc.



The facility is not located within a Sole Source Aquifer area.

EJScreen Report (Version 2.11)

1 mile Ring Centered at 40.549222,-74.421430, NEW JERSEY, EPA Region 2

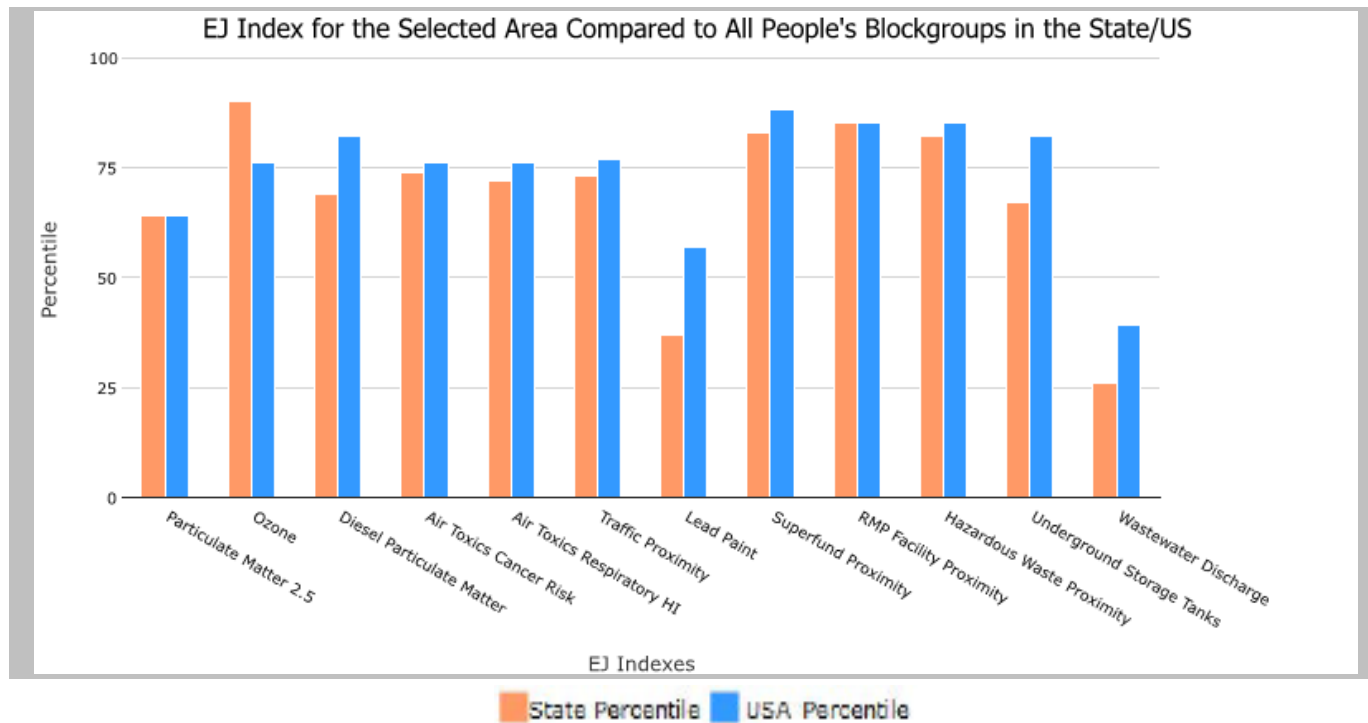
Approximate Population: 7,731

Input Area (sq. miles): 3.14

Sciencetech Laboratories Inc

Selected Variables	State Percentile	USA Percentile
Environmental Justice Indexes		
Particulate Matter 2.5 EJ index	64	64
Ozone EJ index	90	76
Diesel Particulate Matter EJ index*	69	82
Air Toxics Cancer Risk EJ index*	74	76
Air Toxics Respiratory HI EJ index*	72	76
Traffic Proximity EJ index	73	77
Lead Paint EJ index	37	57
Superfund Proximity EJ index	83	88
RMP Facility Proximity EJ index	85	85
Hazardous Waste Proximity EJ index	82	85
Underground Storage Tanks EJ index	67	82
Wastewater Discharge EJ index	26	39

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.



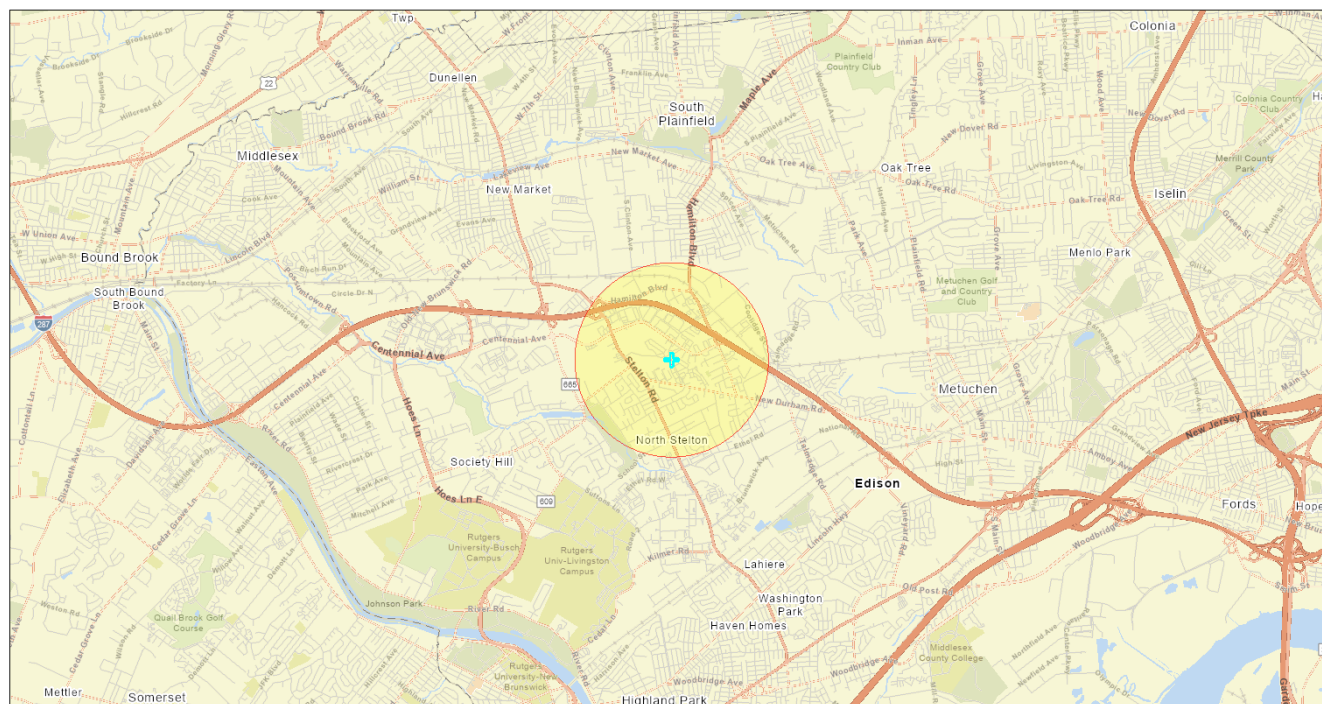
*Diesel particular matter, air toxics cancer risk, and air toxics respiratory hazard index are from the EPA's Air Toxics Data Update, which is the Agency's ongoing, comprehensive evaluation of air toxics in the United States. This effort aims to prioritize air toxics, emission sources, and locations 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>.

1 mile Ring Centered at 40.549222,-74.421430, NEW JERSEY, EPA Region 2

Approximate Population: 7,731

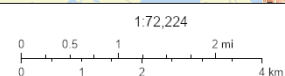
Input Area (sq. miles): 3.14

Sciencet Laboratories Inc



March 28, 2023

Sciencet Laboratories Inc



Somerset County, NJ, New Jersey Office of GIS, Esri, HERE, Garmin, SafeGraph, GeoTechnologies, Inc, METI/NASA, USGS, EPA, NPS, USDA

Sites reporting to EPA	
Superfund NPL	0
Hazardous Waste Treatment, Storage, and Disposal Facilities (TSDF)	7

EJScreen Report (Version 2.11)

1 mile Ring Centered at 40.549222,-74.421430, NEW JERSEY, EPA Region 2

Approximate Population: 7,731

Input Area (sq. miles): 3.14

Sciencetech Laboratories Inc

Selected Variables	Value	State Avg.	%ile in State	USA Avg.	%ile in USA
Pollution and Sources					
Particulate Matter 2.5 ($\mu\text{g}/\text{m}^3$)	8.33	8.34	45	8.67	42
Ozone (ppb)	43	42.1	84	42.5	58
Diesel Particulate Matter* ($\mu\text{g}/\text{m}^3$)	0.478	0.52	56	0.294	80-90th
Air Toxics Cancer Risk* (lifetime risk per million)	40	29	99	28	95-100th
Air Toxics Respiratory HI*	0.4	0.38	78	0.36	80-90th
Traffic Proximity (daily traffic count/distance to road)	770	920	68	760	76
Lead Paint (% Pre-1960 Housing)	0.11	0.4	18	0.27	36
Superfund Proximity (site count/km distance)	1.3	0.45	92	0.13	98
RMP Facility Proximity (facility count/km distance)	2.9	0.76	93	0.77	95
Hazardous Waste Proximity (facility count/km distance)	11	3.3	93	2.2	96
Underground Storage Tanks (count/km ²)	9.6	15	55	3.9	88
Wastewater Discharge (toxicity-weighted concentration/m distance)	1.7E-05	0.24	12	12	20
Socioeconomic Indicators					
Demographic Index	44%	33%	70	35%	69
Supplemental Demographic Index	8%	12%	34	15%	22
People of Color	82%	45%	82	40%	84
Low Income	6%	22%	22	30%	9
Unemployment Rate	8%	6%	73	5%	74
Limited English Speaking Households	4%	7%	58	5%	72
Less Than High School Education	7%	10%	54	12%	45
Under Age 5	4%	6%	45	6%	43
Over Age 64	17%	16%	60	16%	56
Low Life Expectancy	16%	18%	22	20%	14

EJScreen is a screening tool for pre-decisional use only. It can help identify areas that may warrant additional consideration, analysis, or outreach. It does not provide a basis for decision-making, but it may help identify potential areas of EJ concern. Users should keep in mind that screening tools are subject to substantial uncertainty in their demographic and environmental data, particularly when looking at small geographic areas. Important caveats and uncertainties apply to this screening-level information, so it is essential to understand the limitations on appropriate interpretations and applications of these indicators. Please see EJScreen documentation for discussion of these issues before using reports. This screening tool does not provide data on every environmental impact and demographic factor that may be relevant to a particular location. EJScreen outputs should be supplemented with additional information and local knowledge before taking any action to address potential EJ concerns.

1 mile Ring Centered at 40.549222,-74.421430, NEW JERSEY, EPA Region 2

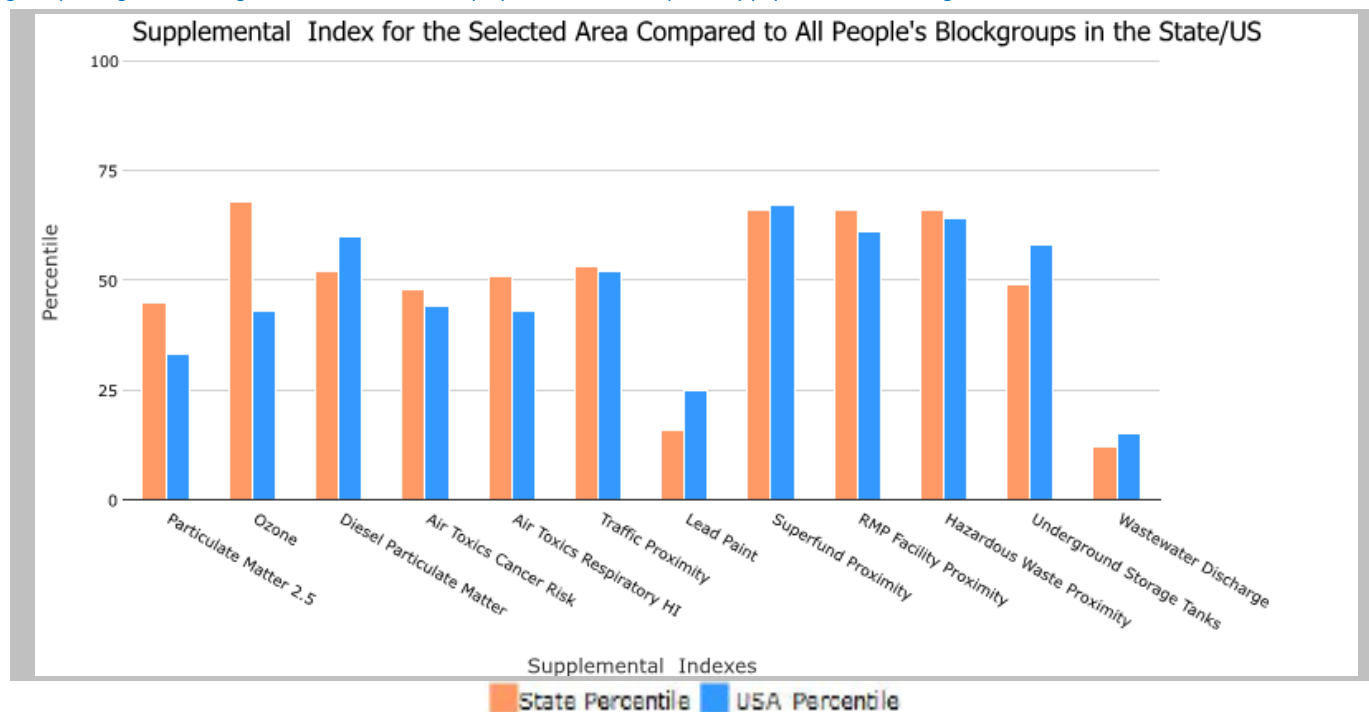
Approximate Population: 7,731

Input Area (sq. miles): 3.14

Scientech Laboratories Inc

Selected Variables	State Percentile	USA Percentile
Supplemental Indexes		
Particulate Matter 2.5 Supplemental Index	45	33
Ozone Supplemental Index	68	43
Diesel Particulate Matter Supplemental Index*	52	60
Air Toxics Cancer Risk Supplemental Index*	48	44
Air Toxics Respiratory HI Supplemental Index*	51	43
Traffic Proximity Supplemental Index	53	52
Lead Paint Supplemental Index	16	25
Superfund Proximity Supplemental Index	66	67
RMP Facility Proximity Supplemental Index	66	61
Hazardous Waste Proximity Supplemental Index	66	64
Underground Storage Tanks Supplemental Index	49	58
Wastewater Discharge Supplemental Index	12	15

Supplemental Indexes - The supplemental indexes offer a different perspective on community-level vulnerability. They combine data on low-income, limited English speaking, less than high school education, unemployed, and low life expectancy populations with a single environmental indicator.



This report shows the values for environmental and demographic indicators, EJScreen indexes, and supplemental indexes. It shows environmental and demographic raw data (e.g., the estimated concentration of ozone in the air), and also shows what percentile each raw data value represents. These percentiles provide perspective on how the selected block group or buffer area compares to the entire state, EPA region, or nation. For example, if a given location is at the 95th percentile nationwide, this means that only 5 percent of the US population has a higher block group value than the average person in the location being analyzed. The years for which the data are available, and the methods used, vary across these indicators. Important caveats and uncertainties apply to this screening-level information, so it is essential to understand the limitations on appropriate interpretations and applications of these indicators. Please see EJScreen documentation for discussion of these issues before using reports. For additional information, see: www.epa.gov/environmentaljustice.