



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Four Penn Center
1600 JFK Blvd.
Philadelphia, Pennsylvania 19103-2029**

Report Title: Clean Water Act Compliance Inspection Report
Inspection Date(s): 09/22/2023
Regulatory Program(s): National Pollutant Discharge Elimination System (NPDES)
Type of Activity: Industrial Wastewater and Industrial Stormwater
Site/Facility Name: SPI Pharma, Inc.
Permittee(s): SPI Pharma, Inc.
Site/Facility Operator: SPI Pharma, Inc.
Site/Facility Address: 40 Cape Henlopen Drive
Lewes, DE 19958
Latitude: 38.790952 **Longitude:** -75.103954
County: Sussex County
Permit Number: DE0000060
NAICS Code: 325412 **SIC:** 2834
Unique Project #: 3E23WN126A

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Unique Project Identifier (UPI): 3E23WN126A

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- Attachment A: Individual NPDES Permit DE0000060**
- Attachment B: Photograph Log**
- Attachment C: Numeric Limit Exceedances for Outfall 001**
- Attachment D: Facility SWP**
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I. INTRODUCTION

On September 22, 2023, representatives from EPA Region 3 (hereinafter, referred to as the “EPA Inspection Team”) conducted an industrial wastewater and industrial stormwater compliance evaluation inspection at the SPI Pharma Inc. facility located at 40 Cape Henlopen Drive in Lewes, Delaware (hereinafter, “the Facility”). SPI Pharma, Inc. is the Permittee and owns and operates the Facility (hereinafter, “the Permittee”). Representatives from the Delaware Department of Natural Resources and Environmental Control (DNREC) also attended the inspection. The purpose of the inspection was to assess the Permittee’s compliance with the Facility’s National Pollutant Discharge Elimination System (NPDES) Permit No. DE0000060 (hereinafter, “the Permit”).

II. INSPECTION

A. Opening Conference

The EPA Inspection Team arrive at the Facility at approximately 9:15 AM (EDT). The inspection involved the following people:

Table 1: Inspection Participants

Name	Affiliation	Telephone	Email
Chuck Schadel, Inspector	USEPA Region 3	215-814-5761	schadel.chuck@epa.gov
Shane McAleer, Inspector	USEPA Region 3	215-814-5616	mcaleer.shane@epa.gov
Brian Winship, Site Manager	SPI Pharma	302-360-7273	bwinship@spipharma.com
Paul Swarm, EHS Manager	SPI Pharma	717-344-4556	pswarm@spipharma.com
Nicole Smith, Environmental Scientist IV	DNREC, Resource Protection Section	302-739-9945	nicole.smith@delaware.gov

Chuck Schadel and Shane McAleer displayed their credentials to the Facility representatives at the outset of the inspection, and explained the purpose of the inspection was to observe compliance with its Permit. A copy of the Permit is provided in Appendix A. The EPA Inspection Team informed the Facility representatives that any information that the Facility deemed to be confidential business information (“CBI”) should be identified to EPA representatives during the inspection and it would be handled as CBI according to EPA’s CBI procedures.

B. Weather and Precipitation

At the time of the inspection, the weather was partly cloudy skies with a maximum temperature of approximately 80 degrees Fahrenheit; no precipitation was experienced during the inspection. National Oceanic and Atmospheric Administration (NOAA) National Weather Service precipitation data for the date of the inspection and 5 days prior are provided in the table below.

Table. 2 Precipitation Preceding Inspection¹

Station Name	Date	Precipitation Amount (inches) ²
LEWES 3.9 SW, DE US US1DESS0044	9/17/2023	0.00
LEWES 3.9 SW, DE US US1DESS0044	9/18/2023	1.23
LEWES 3.9 SW, DE US US1DESS0044	9/19/2023	0.10
LEWES 3.9 SW, DE US US1DESS0044	9/20/2023	0.00
LEWES 3.9 SW, DE US US1DESS0044	9/21/2023	0.00
LEWES 3.9 SW, DE US US1DESS0044	9/22/2023	0.00

C. Summary of the Facility

The Facility is located at 40 Cape Henlopen Drive in Lewes, Delaware, near the Delaware Bay. Prior to July 1998, the site was owned and operated by Rhone-Poulenc Rorer. SPI Pharma manufactures aluminum hydroxide and magnesium hydroxide for pharmaceutical antacid applications. The standard industrial classification code for the site is 2834, antacid preparations manufacturing. The facility grounds are divided into 4 drainage areas, each with a distinct storm water outfall. The Facility discharges wastewater and stormwater to the Delaware Bay, either directly or via mosquito control ditch (to the Lewes Canal). Attachment A shows the location of the facility with respect to the Delaware Bay. The site is fenced with pass card gate access.

The Facility (Figure 1) encompasses about 13 acres of industrial activity exposed to storm water. The site is divided into 4 storm water drainage areas, each with its own outfall. Outfall 001 is a combined process and storm water discharge, and handles the majority of the site's storm water discharge. Outfall 002 handles storm water runoff from the front of the facility's lawn and roof drainage from the 14,000-sq. ft. warehouse and 3,450-sq. ft. of office. Outfall 003 receives runoff from the front third of the employee parking lot – about 2,000-sq. ft. of paved area. Outfall 004 drains a maintenance and material storage area of 85,000-sq. ft., which is also paved. See Attachment D - Storm Water Plan, for additional detail on the four outfalls.

This plant produces calcium carbonate, magnesium hydroxide, and aluminum hydroxide that is used in the manufacturing of antacid medications. The primary chemical, magnesium, is extracted from sea water. Sea water is brought into the plant and treated, and magnesium is precipitated and settled in tanks. The magnesium hydroxide slurry is then pumped to a Rotary Vacuum Filter where water is removed. All supernatant from the thickener tanks goes to the Settling Ponds. All internal drains from the entire process area are directed to a main sump, and this main sump is pumped to the Hydro-Treater (a large tank for settling). Settled sludge from the Hydro-Treater is sent to a separate sludge filter. Sludge cake from this filtering process is sent to outside storage and later distributed for land application on farmlands.

Supernatant from thickener tanks and the Hydro-Treater is sent to two (2) Spill/Settling Ponds to allow solids to settle. All water and supernatant are then sent to the settling ponds to remove solids.

¹ Source: NOAA National Climatic Data Center (<http://www.ncdc.noaa.gov/>).



Figure 1- Facility Map

III. OBSERVATIONS

As part of the inspection, the EPA Inspection Team visually observed Facility conditions and documented those conditions through photographs in the presence of the Facility representatives (refer to [Appendix B, Photo Log](#)). Photographs were taken during the inspection and are provided in Appendix – B. The photographs for this report have been processed using EPA Region 3 's Photo Management Process. A file name (e.g., 2023-09-22--09.39.26_DSCN3857) which incorporates the date and time the photo was taken (e.g., 2023-09-22--09.39.26_DSCN3857), as well as the original camera generated file name (e.g., DSCN3857) is assigned to each photo as part of the process. The file names generated by the camera are used to identify each photo in the Main Narrative and Photo Log of this inspection report. Unused photos are digitally stored and maintained in the inspection file. Unused photos are available upon request.

**The NPDES Permit, Part 1, B. Effluent Limitations and Monitoring Requirements,
1. EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS for Outfall 001**

Parameter	Effluent Limitations						Monitoring Requirements ⁽²⁾	
	Load			Concentration			Measurement Frequency	Sample Type
	Daily Average	Daily Maximum	Units	Daily Average	Daily Maximum	Units		
Flow			MGD	---			Continuous	Record/ Totalize
Total Suspended Solids	661.0	991.4	lbs/day	30.0	45.0	mg/L	Once per week	Composite
Aluminum, Total			lbs/day			mg/L	Once per quarter	Composite
pH	The pH shall be between 6.0 S.U. and 9.0 S.U at all times					S.U.	5 days per week	Grab
The discharge shall be free from floating solids, sludge deposits, debris, oil and scum.								

Observation 1 –

According to EPA's ICIS database, the Facility experienced 17 effluent limit exceedances for Total Suspended Solids from Outfall 001, between November 1, 2018 and February 28, 2023 (refer to [Appendix C](#)). Flows from the process and production area (Photos DSCN3863 and 3869), including stormwater, are collected at a main sump (Photo DSCN3867). Monitoring is performed after these flow passes through the two settling basins at the facility (Photos DSCN3859, DSCN3860, DSCN3870 and DSCN72). Photo DSCN3862 provides a view of the automated sampler at the monitoring location at the discharge point of Basin #2 (Outfall 001).

The NPDES Permit, Part III, A. Special Conditions, 3. Storm Water Plan

"The permittee shall continue to implement and maintain a Storm Water Plan (SWP) that is designed to limit the exposure of industrial materials and activities to precipitation and to minimize the discharge of contaminated storm water from the permittee's facility. The SWP shall be implemented and maintained in accordance with the requirements in the Department's *Regulations Governing the Control of Water Pollution*, §9.1.5, "Storm Water Plan (SWP)". In particular, the SWP shall address practices including good housekeeping, inspections under wet and dry weather conditions, sediment and erosion control, facility security and managing runoff. The permittee shall also comply with the requirements for storm water monitoring referenced in §9.1.5.7.5, in accordance with §9.1.4. An updated SWP must be submitted for Department approval within 120 days following the effective date of this permit."

Observation 2 –

The Permittee provided the documents located in Appendix D to demonstrate compliance with this requirement. The SWP appears to address all practices required by the Permit. However, the SWP is not signed nor dated.

**The NPDES Permit, Part III, A. Special Conditions, 3. Storm Water Plan;
Storm Water Plan - Part III. BEST MANAGEMENT PRACTICES, B. Good Housekeeping**

“A clean and orderly work area reduces the potential for accidental spills and minimizes significant materials that may be exposed to storm water

...

The housekeeping program addresses specific measures aimed at reducing the possibility of storm water mixing with pollutants...

1. Operations and Maintenance

...

- d. Routinely inspect for leaks or conditions that could lead to discharges of chemicals or contact storm water with raw materials, intermediate material, waste materials, or products.”

Observation 3 –

Photos DSCN3873, 3874, 3877 and 3878 show a white material that is stored at the Facility. According to the Facility representatives, this is a waste product from the Facility process that contains residual calcium and magnesium solids.

The NPDES Permit, Part III, A. Special Conditions, 4. Total Nitrogen (N), Total Phosphorus (P) and Enterococcus Monitoring (Outfall Monitoring for 002, 003 & 004)

“Monitoring for N, P and enterococcus shall be conducted semi-annually during wet weather events at Outfalls 002, 003, and 004. All samples shall be collected from the discharge resulting from a storm that is greater than 0.1 inches and at least 72 consecutive hours later than the previous measurable (greater than 0.1 inch) storm. All samples shall be taken within 30 minutes after discharge begins or as soon thereafter as practicable. No sample shall be taken under circumstances that have the potential to endanger the sampler (underlined for emphasis). Analytical results shall be submitted to the Department as a separate report (email acceptable) within 30 days of sampling. The Department will analyze the data and may modify the monitoring frequency based on the results of the analysis. The Department will consider the long-term TMDL target concentrations of 3.0 mg/L N and 0.2 mg/L P, and the bacterial water quality criteria in evaluating the data.”

Observation 4 -

The Permittee stated that conditions for collecting monitoring samples at the monitoring locations presents an unsafe situation due to the unstable stream bed and high embankments straddling the discharge location and the issue is being discussed with DNREC. At this time, no stormwater monitoring data has been provided to EPA Region 3.

**The NPDES Permit, Part III, A. Special Conditions, 3. Storm Water Plan;
Storm Water Plan - Part III. BEST MANAGEMENT PRACTICES, D. Visual Inspection**

“Preventing pollution of storm water runoff requires good housekeeping in areas where materials are handled, stored, or transferred and preventive maintenance systems of process equipment and systems. These practices are described in detail above. Regular visual inspections are essential to ensure that all of the elements of the SWP are in place and working properly. Visual inspections are to be conducted at a minimum of quarterly and are an integral part of the housekeeping programs that are currently in place and are to be implemented.

...

“Visual inspection for potential pollutants will include at least the following areas:

1. Area around all outside process equipment.
2. Areas where spills and leaks have occurred in the past.
3. Material storage areas (above ground tanks, drum storage, tote storage).
4. Material loading, unloading and transfer areas.
5. Outfalls 002,003 and 004.”

Observation 5 -

The Permittee provided the documents located in Appendix E to demonstrate compliance with this requirement. Quarterly Visual inspections (Attachment E) are being conducted and recorded based on information provided by the Permittee.

**The NPDES Permit, Part III, A. Special Conditions, 3. Storm Water Plan;
Storm Water Plan - Part IV. IMPLEMENTATION, B. Employee Training**

“Employee training is essential to the effective implementation of the PPP. The goal of the training program is to teach personnel, at all levels of responsibility, the components and goals of the SWP.

...

4. Training Records

A training program record will be maintained to document all training related to the SWP received at the facility. The records will be maintained in the Employee Training Records Manual. The Storm Water Plan Team will also regularly evaluate the effectiveness of the training efforts.”

Observation 6 -

The Permittee provided the documents located in Appendix F to demonstrate compliance with this Permit requirement.

**The NPDES Permit, Part III, A. Special Conditions, 3. Storm Water Plan;
Storm Water Plan - Part V. EVALUATION AND MONITORING, A. Annual Site Compliance Evaluation**

“The annual compliance evaluation will provide the basis for evaluating the overall effectiveness of the SWP. The specific goals of the evaluation will be to verify that the description of potential pollutant sources contained in the plan is accurate; that the plan drainage map is accurate and has been updated to reflect current conditions; and that controls identified in the plan to reduce pollutants in storm water discharges are accurately identified, in-place and working. The evaluation will also identify where new controls are needed so that they may be implemented and incorporated into the SWP.

...

In conducting the annual site compliance evaluation, the Pollution Prevention Team will:

1. Review the SWP and those items that are part of material handling, storage and transfer areas, covered by the plan.
2. Inspect all equipment and containment in these areas covered by the plan.
3. Review facility operations for the past year to determine if any additional areas should be included in the original SWP or if any existing areas were modified so as to require plan modification as appropriate...”

Observation 7 -

The Permittee provided the documents located in Appendix G to demonstrate compliance with this requirement.

IV. CLOSING CONFERENCE

After the inspecting the Facility, the EPA Inspection Team met with the Facility representatives for a closing conference. The EPA Inspection Team shared their preliminary observations with the facility. The EPA Inspection Team reiterated to the Facility representatives that all preliminary observations discussed were not compliance determinations. Any and all preliminary observations shared were subject to further investigation by EPA upon the additional review of records and documentation. Additional observations may be contained in this inspection report that were not identified at the time of the closing conference after EPA review additional materials following the inspection.

The inspection concluded at approximately 11:45 AM (EDT).