



STATE OF DELAWARE

**DEPARTMENT OF NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL**

DIVISION OF WATER

RICHARDSON & ROBBINS BUILDING

89 KINGS HIGHWAY

DOVER, DELAWARE 19901

**SURFACE
WATER
DISCHARGES**

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Public Notice Draft FACT SHEET – June 3, 2020

SPI Pharma, Inc.
40 Cape Henlopen Drive
Lewes, DE 19958

NPDES Permit No. DE 0000060
State Permit No. WPCC 3119H/74

SPI Pharma, Inc. has applied for reissuance of its National Pollutant Discharge Elimination System (NPDES) permit to discharge treated process wastewater into the Delaware Bay and storm water to the Lewes-Rehoboth Canal.

Proposed Changes

1. Revised "Reporting" in Part I.D which requires the Permittee to submit results via the Department approved Electronically Generated Discharge Monitoring Report (eDMR).
2. Deleted effluent limits for average daily flow for outfall 001, in favor of a note stating, "A daily average discharge rate of 2.64 million gallons per day (MGD) was used in determining the effluent limitations for Outfall 001."
3. Added a standard condition in Part II.A.2 "Notifications Specific to Manufacturing, Commercial, Mining, and Silvicultural Dischargers".
4. Added a New Special Condition No. 4 requiring the permittee to monitor nutrients and bacteria at Outfalls 002, 003, and 004.
5. Added New Special Condition No. 9 requiring the permittee to conduct a Whole Effluent Toxicity (WET) test to evaluate whether or not toxicity is a parameter of concern (POC) for effluent discharge at Outfall 001.
6. Added New Special Condition No. 10 based on our review of 40 CFR Part 136 to ensure the use of EPA-approved analytical methods that are capable of detecting and measuring the pollutants at, or below, the applicable water quality criteria or permit limits.

Facility Location

This facility is located at 40 Cape Henlopen Drive in Lewes, Sussex County, Delaware.

Activity Description

The company produces calcium carbonate, magnesium hydroxide and aluminum hydroxide, which are used in the manufacture of antacid medication. The treatment of process water consists of gravity sedimentation and necessary pH adjustments in the ponds prior to discharge.

Discharge Description

Four (4) discharges (Outfalls 001, 002, 003 and 004) are identified in the permit. Outfall 001 consists of treated process wastewater, which has received pH adjustment and solids settling. Outfall 002, 003 and 004 consist of storm water runoff.

Receiving Stream Classification

The facility has four outfalls. One outfall (Outfall 001), process water, flows into the Delaware Bay. The designated uses of the receiving waters in the area of the discharge are industrial water supply; primary and secondary contact recreation; fish, aquatic life & wildlife.

On December 4, 2013, the Delaware River Basin Commission (DRBC) adopted updated water quality criteria for polychlorinated biphenyls (PCBs) in the Delaware Estuary and Bay. The updated PCB criteria for the protection of human health from carcinogenic effects are 16 pg/L. This number, based upon the most current methodology and scientific data available, is now a uniform value for the entire Delaware Estuary and Bay (DRBC Water Quality Zones 2-6). Delaware Bay is under zone 6. Table 1 summarizes the PCB Total Maximum Daily Loads (TMDL) for Zone 6 of Delaware Estuary as well as the allocations to Waste Load Allocations (WLAs) for point source discharges, Load Allocations (LAs) for nonpoint sources, and a Margin of Safety (MOS).

Table 1: TMDL for penta-PCBs and Total PCBs for Zone 6 (Delaware Bay) in milligrams per day.

	TMDL (mg/day)	WLAs (mg/day)	LAs (mg/day)	MOS (mg/day)
Penta-PCB	469.11	3.28	442.38	23.46
Total PCB	1876.45	13.12	1769.51	93.82

Eight NPDES point source discharger have been identified for individual allocations, which does not include any requirements for SPI Pharma, Inc. SPI Pharma is not considered a source of PCB's or pollutants identified in the DRBC and DNREC 303(d) List as needing TMDL's. From the time this site became operational in 1969 to the present, antacid production has utilized an inorganic manufacturing process resulting in magnesium and aluminum hydroxide production. While the production process has no reasonable potential to create or release PCB's, we also looked at their associated use of electrical transformers. Based on a November 4, 2014, document from SPI Pharma, Inc., there is no history of any release of dielectric fluids from transformers in use prior to 2004. Since 2004, four (4) PCB-free transformers were purchased and are the only transformers in use today, as indicated in the supporting documentation provided. Further, veteran employees, with 30+ years on the job at this site, recall no transformer releases or environmental clean-up actions associated with PCB's. Offshore sediment samples from the DRBC support this conclusion.

The three remaining outfalls (Outfall 002, 003 and 004) only discharge stormwater into mosquito control ditches which ultimately drain into the Lewes-Rehoboth Canal, part of the Inland Bays Drainage Basin. Water quality monitoring performed by DNREC has shown that the waters of the Inland Bays Drainage Basin (Buntings Branch, Little Assawoman Bay, Assawoman Bay, Indian River Bay, Iron Branch, Indian River, Rehoboth Bay, and Lewes-Rehoboth Canal Watersheds) are impaired by high levels of bacteria and that the designated uses are not fully supported due to levels of this pollutant in these waters. DNREC listed the Inland Bays Drainage Basin on several of the State's 303(d) Lists and proposes the following TMDLs regulation for *enterococcus* bacteria.

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- The nonpoint source bacteria load in the freshwater portion of the Inland Bays Drainage Basin shall be reduced by 40 percent from the 2000-2005 baseline level.
- The nonpoint source bacteria load in the marine water portion of the Inland Bays Drainage Basin shall be reduced by 23 percent from the 2000-2005 baseline level.
- All point source bacteria loading in the Inland Bays Drainage Basin will be capped at the current, geometric mean concentration level of 35 CFU enterococcus/100mL until all point sources are eliminated as required in the 1998 Inland Bays Nutrient TMDL Regulation.

In addition, TMDLs exist for nutrients for the Indian River, Indian River Bay and the Rehoboth Bay. The Department’s review did not indicate any monitoring requirements. Based on regular site inspections by Senior Environmental Compliance Specialists and others, the exterior portions of the industrial site are paved or covered in crushed stone, so during storm events, there is no reasonable potential that additional nutrients or bacteria will be discharged to the Lewes-Rehoboth Canal. However, the Department still ask for additional monitoring. Then the Department will consider the long-term TMDL target concentrations of 3.20 mg/L total Nitrogen (N) and 0.10 mg/L total Phosphorus (P), and the bacterial water quality criteria in evaluating the data collected in the future.

Statutory and Regulatory Basis

The Delaware Department of Natural Resources and Environmental Control (DNREC) proposes to reissue an NPDES permit to discharge the wastewater subject to certain effluent discharge limitations, monitoring requirements and other terms and conditions identified in the permit. Section 402 of the federal Clean Water Act, as amended, and 7 Del. C. Chapter 60 provide the authority for permit issuance. Federal and state regulations promulgated pursuant to these statutes are the regulatory bases for permit issuance.

Bases for Effluent Limitations

DNREC has examined the application, recent discharge monitoring data and related information. The Department proposes to reissue the facility’s NPDES permit for a period not to exceed five (5) years, subject to the effluent discharge limitations and monitoring requirements shown in the attached permit.

The following table indicates the bases for the effluent limitations for Outfall 001:

Table 2: Bases for Effluent Limitations – Outfall 001			
Parameter	Water Quality- Based	Technology Based	Monitoring Only
Flow			X
pH	SWQS ⁽¹⁾ §4.5.3		
Total Recoverable Aluminum			X
Total Suspended Solids (TSS)		RGCWP ⁽²⁾ §7.3.1	
1. State of Delaware, Surface Water Quality Standards (SWQS) 2. State of Delaware, Regulations Governing the Control of Water Pollution (RGCWP)			

Flow

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The current permit included a daily average effluent flow limitation of 2.64 million gallons per day (MGD) based on the processed water volume of this facility. The proposed permit deletes the flow limitation for average daily flow in favor of a note stating, "The hydraulic design discharge rate of 2.64 MGD was used in determining the effluent limitations for this outfall."

pH

The current permit includes water quality-based effluent limitations and monitoring requirements for pH based on the State of Delaware Surface Water Standards (SWQS), as amended, July 11, 2004. Section 4.5.3 of the current SWQS includes that pH shall be between 6.0-9.0. The proposed monitoring requirements for pH is 5 days per week, which has also been retained from the current permit.

TSS

Technology-based TSS limits and once weekly monitoring requirements have been retained from the current permit. These limits are based on Section 7.3.1 of Regulations Governing the Control of Water Pollution (RGCWP).

Total Recoverable Aluminum

Effluent monitoring for Total Aluminum is also proposed to be retained from the current permit. This monitoring requirement is not specified for this industry category but is required in the permit based on Best Professional Judgment regarding potential for pollutants to be present.

Nutrients, Bacteria Monitoring for Outfall 002, 003, 004

The facility maintains three point sources (Outfall 002, 003, 004) that discharge storm water into mosquito control ditches which ultimately drain into the Lewes-Rehoboth Canal, which is part of the Inland Bays Drainage Basin. TMDLs for nutrients and bacteria exist. Even though there is no reasonable potential that nutrients or bacteria source will be discharged to the Lewes-Rehoboth Canal, the proposed permit includes a new special condition which requires the facility to monitor Total Nitrogen (N), Total Phosphorous (P) and bacteria on a semi-annual basis. At least one round of sampling for N, P and bacteria will help the Department determine whether the site discharges pollutants that contribute to the impairment of the Inland Bay. If the concentration of these pollutants is not significant in the first round of sampling, the permittee may request approval from the Department to discontinue monitoring.

Special Conditions

Special Condition No. 1 states that this permit supersedes NPDES Permit DE 0000060 and State Permit WPCC 3119G/74, issued on January 22, 2015, with an effective date of March 1, 2015.

Special Condition No. 2 is a standard permit reopener clause. This special condition allows the Department to reopen and modify the permit if the discharger is causing water quality problems.

Special Condition No. 3 requires the permittee to continue to implement and maintain a Storm Water Plan (SWP) to minimize the discharge of contaminated storm water from its facility.

Special Condition No. 4 requires the permittee to monitor nutrients and bacteria to determine whether the discharge contributes to the impairment of the Inland Bays Drainage Basin.

Special Condition No. 5 provides information on wastewater treatment plant operator licensing.

Special Condition No. 6, 7 and 8 require proper disposal of sludge in accordance with State and Federal requirements.

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Special Condition No. 9 requires the permittee to conduct a Whole Effluent Toxicity (WET) test to evaluate whether or not toxicity is a parameter of concern (POC) for effluent discharge at Outfall 001.

Special Condition No. 10 requires the permittee to use EPA-approved analytical methods that are capable of detecting and measuring the pollutants at, or below, the applicable water quality criteria or permit limits pursuant to 40 CFR Part 136.

Antidegradation Statement

The proposed effluent limitations included in this NPDES permit comply with the applicable portions of the State of Delaware Surface Water Quality Standards, Section 5: Antidegradation and ERES Waters Policies.

Public Notice and Process for Reaching a Final Decision

The public notice of the Department's receipt of the application and of reaching the tentative determinations outlined herein will be published in the Wilmington News Journal and the Delaware State News on **May 31, 2020**. Interested persons are invited to submit their written views on the draft permit and the tentative determinations made with respect to this NPDES permit application. The Department will not hold a public hearing on this application unless the Department receives a meritorious request to do so or unless the notice of this proposal generates substantial public interest. A public hearing request shall be deemed meritorious if it exhibits a familiarity with the application and a reasoned statement of the permit's probable impact. The request for a public hearing shall be in writing and shall state the nature of the issues to be raised at the hearing. All comments received by 4:30 p.m. on **June 30, 2020** will be considered by the Department in preparing the final permit.

Department Contact for Additional Information:

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