pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Northeast Regional Office
CLEAN WATER PROGRAM

Application Type	**Renewal**	Application No.	**PA0060071**
Facility Type	**Industrial**	APS ID	**555203**
Major / Minor	**Minor**	Authorization ID	**1395429**

NPDES PERMIT FACT SHEET INDIVIDUAL INDUSTRIAL WASTE (IW) AND IW STORMWATER

Applicant and Facility Information

Applicant Name	**Sanofi Pasteur, Inc.**	Facility Name	**Sanofi Pasteur, Inc.**
Applicant Address	Discovery Drive Swiftwater, PA 18370-0187	Facility Address	Discovery Drive Swiftwater, PA 18370-0187
Applicant Contact	Joseph Gilliland	Facility Contact	Joseph Gilliland
Applicant Phone	(570) 957-2205	Facility Phone	(570) 957-2205
Client ID	93312	Site ID	2571
SIC Code	2834,2836	Municipality	Pocono Township
SIC Description	Manufacturing - Biological Products, Except Diagnostic, Manufacturing - Pharmaceutical Preparations	County	Monroe
Date Application Received	May 6, 2022	EPA Waived?	Yes
Date Application Accepted	May 6, 2022	If No, Reason	-
Purpose of Application	Renewal of NPDES permit.		

Summary of Review

The applicant is requesting the renewal of their NPDES permit to discharge treated industrial wastewater and sewage from Outfall 001 into Swiftwater Creek, a High Quality - Cold Water Fishes, Migratory Fishes (HQ-CWF, MF) receiving stream. Per the Department's current existing use list, this section of Swiftwater Creek does not have an existing use classification that is more protective than the designated use. Swiftwater Creek is classified as an Exceptional Value (EV) stream from its source to a point approximately 1 mile upstream of the discharge. The discharge will be modeled using the same value as used in the previous renewal (0.55 MGD). Data from the permit renewal application indicates a maximum flow of 0.5 MGD through Outfall 001.

Existing Requirements

This facility manufactures pharmaceutical drugs and is considered a Minor IW facility with ELGs. The discharge from Outfall 001 consists of treated process wastewater, cooling tower and boiler blowdown, and sanitary sewage waste streams. The discharge is subject to EPA's Title 40: Protection of Environment, Part 439 - Pharmaceutical Manufacturing Point Source Category under the following subparts:

Subpart A - Fermentation Products - This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by fermentation. *Fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.

§439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Approve	Deny	Signatures	Date
X		Brian Burden, E.I.T. / Project Manager	July 1, 2024
X		Amy M. Bellanca (signed) Amy M. Bellanca, P.E. / Program Manager	7-8-24

Summary of Review

(a) The maximum monthly average limitation for BOD_5, expressed as mass loading (lbs., kg) per day, must reflect not less than 90 percent reduction in the long-term average daily BOD_5 load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

(1) The long-term average daily BOD_5 load of the raw process wastewater (*i.e.*, the base number to which the percent reduction is applied) is defined as the average daily BOD_5 load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. These residual amounts may be included in the calculation of the average influent BOD_5 loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from waste streams; incineration of concentrated solvent wastestreams (including tar still bottoms); and concentration of broth for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 may be achieved by any of several, or a combination, of these practices.

(b) The maximum monthly average limitation for TSS, expressed as mass loading (lbs., kg) per day, must be calculated as 1.7 times the BOD_5 limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the limitations for COD are as follows:

Regulated parameter	Maximum daily (mg/L)	Maximum monthly average (mg/L)
COD	1675	856

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the monthly average limitation for COD corresponding to the lower concentration value must be applied.

(e) The effluent limitations for cyanide are as follows:

Regulated parameter	Maximum daily (mg/L)	Maximum monthly average (mg/L)
Cyanide (T)	33.5	9.4

(f) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide effluent limitations in paragraph (e) of this section must be demonstrated at in-plant monitoring points pursuant to 40 CFR 122.44(i) and 122.45(h). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(g) Compliance with the limitation in paragraph (e) or (f) of this section may be achieved by certifying to the permit issuing authority that the facility's manufacturing processes neither use nor generate cyanide.

§439.13 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Summary of Review

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in §439.12.

§439.14 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

Regulated parameter	Maximum daily (mg/L)	Maximum monthly average (mg/L)
Ammonia (as N)	84.1	29.4
Acetone	0.5	0.2
4-methyl-2-pentanone	0.5	0.2
Isobutyraldehyde	1.2	0.5
n-Amyl acetate	1.3	0.5
n-Butyl acetate	1.3	0.5
Ethyl acetate	1.3	0.5
Isopropyl acetate	1.3	0.5
Methyl formate	1.3	0.5
Amyl alcohol	10.0	4.1
Ethanol	10.0	4.1
Isopropanol	3.9	1.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Dimethyl sulfoxide	91.5	37.5
Triethyl amine	250.0	102.0
Phenol	0.05	0.02
Benzene	0.05	0.02
Toluene	0.06	0.02
Xylenes	0.03	0.01
n-Hexane	0.03	0.02
n-Heptane	0.05	0.02
Methylene chloride	0.9	0.3
Chloroform	0.02	0.13
1,2-dichloroethane	0.4	0.1
Chlorobenzene	0.15	0.06
o-Dichlorobenzene	0.15	0.06
Tetrahydrofuran	8.4	2.6
Isopropyl ether	8.4	2.6
Diethyl amine	250.0	102.0
Acetonitrile	25.0	10.2

(b) The limitations for COD are the same as specified in §439.12(c) and (d).

Summary of Review

(c) The limitations for cyanide are the same as specified in §439.12(e), (f) and (g).

Subpart D - Mixing/Compounding and Formulation - This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by mixing, compounding and formulating operations. *Mixing, compounding, and formulating operations* means processes that put pharmaceutical products in dosage forms. *Product* means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions.

§439.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD_5 is the same as specified in §439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in §439.12(b).

(c) The limitations for COD are the same as specified in §439.22(c) and (d).

§439.43 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD_5, TSS and pH are the same as the corresponding limitations in §439.42.

§439.44 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: The limitations for COD are the same as specified in §439.22(c) and (d).

Subpart E - Research - This subpart applies to discharges of process wastewater resulting from pharmaceutical research. For this subpart, *product* means products or services resulting from research and product development activities.

§439.52 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD_5 is the same as specified in §439.12(a). No facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in §439.12(b).

(c) The maximum monthly average limitation for COD, expressed as mass loading (lbs, kg) per day, must reflect not less than 74 percent reduction in the long-term average daily COD load of the raw (untreated) process wastewater,

Summary of Review

multiplied by a variability factor of 2.2. No facility shall be required to attain a limitation for COD that is less than the equivalent of 220 mg/L.

(d) The long-term average daily BOD_5 or COD mass loading of the raw process wastewater (*i.e.,* the base number to which the percent reduction is applied) is defined as the average daily BOD_5 or COD load during any calendar month, over 12 consecutive months within the most recent 36 months.

(1) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD_5 or COD load in the influent to the wastewater treatment system must exclude any portion of the load associated with solvents, except for residual amounts of solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD_5 or COD loading.

(2) The practices of recovery, and/or separate disposal or reuse include: recovery of solvents from wastestreams; and incineration of concentrated solvent wastestreams (including tar still bottoms). This regulation does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD_5 or COD may be achieved by any of several, or a combination, of these practices.

(e) The pH must be within the range 6.0 to 9.0.

EPA also published an additional permit guidance document dated January 2006 titled “Permit Guidance Document: Pharmaceutical Manufacturing Point Source Category (40 CFR Part 439)” which provides an allowance of up to 25% of non-process water through treatment. Page 8-4 of the document is attached to this fact sheet and explains the provision. The adjusted flows from each process shown below were taken from the 2006 permit renewal application (see attached Table 3) and remain valid:

Source of Wastewater	Flow(gpd)	Adjustment	Adjusted flow (gpd)	% flow
Subparts A and E	600,485	divide by 0.75	800,647	84.3%
Subpart D	95,900	divide by 0.75	127,867	13.4%
Sanitary sewage	253,615	remainder	21,486	2.3%

Total = 950,000 gpd = 0.95 MGD Total = 950,000 gpd = 0.95 MGD

The total wastewater flow generated by the facility is 0.95 MGD of which up to 0.35 MGD is conveyed to the Pocono Township collection system and treated by the POTW. Approximately 0.05 MGD of treated effluent will be reused within the facility, leaving a maximum of 0.55 MGD for stream discharge. To further protect the water quality of Swiftwater Creek, up to 0.313 MGD of treated wastewater will be spray irrigated on a seasonal basis when conditions are suitable between April and October.

The Quantitation Limits (QLs) for Acetonitrile and Dimethyl Sulfoxide are 10 mg/L and 20 mg/L, respectively, as confirmed by Lancaster Laboratories (permittee’s laboratory) during the previous permit term. A special condition is carried over in Part C to address the situation when WQBELs are below the QLs. For compliance purposes, it was previously decided that it is appropriate to cite the water quality-based effluent limitations in Part A of the permit and then enter the QLs in eDMR.

Stormwater

The permittee is authorized to discharge non-polluting stormwater through the outfalls listed in the following table. Stormwater monitoring is required only for Outfalls 010 and 011 since they are considered representative of the remaining outfalls. Monitoring requirements are listed in Part A of the permit for Outfalls 010 and 011, and special conditions and minimum required BMPs applicable to all outfalls and carried over in Part C. Note: Outfall 029 was

Summary of Review

newly identified during this permit renewal. Coordinates in the table below are rounded to the nearest tenth of a second from the coordinates provided in the renewal application.

Outfall No.	Latitude	Longitude	Description
002	41° 05' 38.8"	-75° 19' 20.0"	Administrative, Boiler House and R&D Bldgs.
003	41° 05' 39.3"	-75° 19' 26.5"	R&D and Office Bldgs.
007	41° 05' 40.2"	-75° 19' 35.8"	Reception Bldg. and Parking Lot
008	41° 05' 38.8"	-75° 19' 20.0"	Administrative, Boiler House and R&D Bldgs.
009	41° 05' 40.5"	-75° 19' 33.0"	Lawn
010	41° 05' 39.9"	-75° 19' 33.0"	R&D Bldgs.
011	41° 05' 40.1"	-75° 19' 30.2"	Administrative Bldgs.
012	41° 05' 38.8"	-75° 19' 20.0"	Administrative, Boiler House and R&D Bldgs.
013	41° 05' 38.8"	-75° 19' 20.0"	Administrative, Boiler House and R&D Bldgs.
014	41° 05' 39.8"	-75° 19' 27.3"	Roadway
015	41° 05' 39.5"	-75° 19' 27.0"	Roadway
016	41° 05' 39.3"	-75° 19' 25.7"	R&D Bldgs.
017	41° 05' 38.5"	-75° 19' 24.2"	Open Area
018	41° 05' 38.5"	-75° 19' 21.4"	Production Bldg., Open Area and Roadway
020	41° 05' 37.9"	-75° 19' 17.3"	Production Bldg. and Roadway
021	41° 05' 38.2"	-75° 19' 12.5"	WWTP
022	41° 05' 35.3"	-75° 19' 09.2"	Production, Administrative and WWTP Bldgs.
023	41° 05' 33.5"	-75° 19' 00.7"	Production, Admin., Central Util. Plant Bldgs.
024	41° 05' 33.2"	-75° 18' 55.4"	Main Parking Lot
025	41° 05' 32.6"	-75° 18' 58.1"	Main Parking Lot
026	41° 05' 24.1"	-75° 19' 25.5"	Parking Lot, Roadway and Open Area
027	41° 05' 26.2"	-75° 19' 20.9"	Roadway and Parking
028	41° 05' 35.6"	-75° 19' 01.2"	69 kVA sub station
029	41° 05' 32.8"	-75° 18' 32.4"	Contractor Office, Staging Area, Open Area

Water Quality-Based Limitations

The effluent limits derived by a prior 2006 PENTOXSD model for Total Mercury, 1,2 Dichloroethane and Methylene Chloride remain in the permit to comply with the anti-backsliding policy by maintaining the most stringent effluent limitations. Refer to the 2006 pollution report attachments (includes antidegradation spreadsheet) that were developed for calculation of non-degrading effluent limitations to help protect and maintain water quality and aquatic life in the high-quality receiving stream.

DRBC Docket

DRBC Docket No. D-1999-071-4, approved on September 12, 2013, included the following limitations/requirements that were added to the permit during the previous renewal:

- Fecal Coliform geometric mean 338 No./100 mL (Oct 1 - April 30)
- Total Dissolved Solids monthly average 1,200 mg/L and daily maximum of 1,752 mg/L
- Dissolved Oxygen minimum of 6.0 mg/L
- Total Kjeldahl Nitrogen, Nitrate-Nitrite as N, and TN monthly monitoring/reporting

Summary of Review

New Requirements

Toxics Management Spreadsheet (TMS) / WQM 7.0

The TMS was used to model the Pollutant Group sampling results included in the permit renewal application. Additional parameters with Chapter 93 water quality standards that were identified and detected in the effluent were also modeled with the TMS. The low-flow yield of 0.62 cfs/mi^2 used to model the discharge was generated using data from stream gage 01440485 (Swiftwater Creek at Swiftwater, PA) and is carried over from the previous renewal. For modeling inputs, RMI values were obtained using the "PA Historic Streams" feature of eMapPA as well as the "measure" tool. Drainage areas were delineated using USGS's StreamStats Interactive Map and elevations were obtained using the elevation profile feature of StreamStats (see Watershed Information attachment). Stream hardness was obtained from the renewal application. The TMS recommendations are as follows:

☑ ***Recommended WQBELs & Monitoring Requirements***

No. Samples/Month: 4

	Mass Limits		*Concentration Limits*					
Pollutants	AML (lbs/day)	MDL (lbs/day)	AML	MDL	IMAX	Units	Governing WQBEL	WQBEL Basis
Total Aluminum	13.3	20.7	2,894	4,515	7,236	µg/L	2,894	AFC
Total Cadmium	Report	Report	Report	Report	Report	µg/L	0.79	CFC
Total Copper	Report	Report	Report	Report	Report	µg/L	21.4	AFC
Total Lead	Report	Report	Report	Report	Report	µg/L	5.49	CFC
Total Zinc	Report	Report	Report	Report	Report	µg/L	201	AFC

Since the highest reported Total Aluminum concentration was 1,700 µg/L and it appears the permittee can meet the monthly average limitation is 2,894 µg/L, the limitation will come into effect upon permit issuance. Total Cadmium, Total Copper, Total Lead and Total Zinc are to be monitored on a semiannual basis.

Note: Acrylamide was not detected in the effluent and does not have a target QL assigned by DEP, therefore, it was not included in the TMS modeling.

WQM 7.0 didn't recommend more stringent limitations for BOD_5 / $CBOD_5$, Ammonia-N, or Dissolved Oxygen.

Total Residual Chlorine (TRC)

Since the method of disinfection is Ultraviolet (UV) radiation, the previous permit did not contain TRC limitations in Part A. A special condition was included to address the use of chlorine for general disinfection purposes and to include results in an attachment to the DMR submittals.

During this permit term, IMAX limitations are added to Part A for TRC with a minimum monitoring frequency of "daily when discharging". The permittee shall monitor TRC concentrations in the effluent every day chlorine is used for backup disinfection, cleaning, or other purposes.

DRBC Docket

The latest docket, D-1999-071-6 (approved 6/7/2023), includes the following new requirements that are added to this renewal:

Summary of Review

EFFLUENT TABLE C-2: DRBC Parameters Not Included in NPDES Permit

OUTFALL 001 (Discharging to Swiftwater Creek)		
PARAMETER	**LIMIT**	**MONITORING**
BOD_5 (at 20° C)	Monitor & Report Percent Removal	Monthly
BOD_5 (at 20° C) Influent	Monitor & Report	Monthly

Chemical Additives

The permittee had previously submitted chemical additives notification forms for Nalco 1720, Nalco 7408, NexGuard 22300, 3D Trasar 3DT465, Nalco 73801WR, and H-550. Requests for increase usage of Nalco 1720 and Nalco 7408 were received by DEP in April 2022. Requests to use Steris ProKlenz Booster and Steris CP-310 were received by DEP in June 2022. Justifications were provided for each usage rate and appear to be protective of water quality standards.

Stormwater

Monitoring requirements at Outfalls 010 and 011 are updated to conform with the requirements of Appendix F of the most recent PAG-03 permit. Semiannual monitoring/reporting for Total Nitrogen is added to the permit during this renewal. Monitoring requirements for the nine parameters in the previous renewal is continued.

Benchmark values are included in the permit for pH (9.0 S.U.), Chemical Oxygen Demand (120 mg/L), Total Suspended Solids (100 mg/L), and Nitrate+Nitrite-N (3 mg/L). In the event that stormwater discharge concentrations for a parameter exceeds the benchmark values identified below at the same outfall for two or more consecutive monitoring periods, the permittee shall implement a corrective action plan to reduce the concentrations of the parameters in stormwater discharges in accordance with Part C.IV.G.

Miscellaneous

Current guidance requires E. Coli monitoring/reporting in all sewage discharge permits. Since this facility treats and discharges sewage, semi-annual monitoring/reporting requirements are included in the permit for E. Coli at Outfall 001.

All Part C special conditions from the previous issued permit are carried over in this renewal, except for the condition detailing the compliance schedule for meeting the Nitrate-Nitrite as N limitation.

Watershed Information.pdf
TMS PA0060071.pdf
TRC Calculation.pdf
Existing Limitations.pdf
Limitation Comparisons.pdf
TBEL Calculations.pdf
2006 Pollution Report 1.pdf
2006 Pollution Report 2.pdf
2006 Pollution Report 3.pdf
Table 3.pdf
Page 8-4.pdf
Docket 1999-071-6.pdf

Public Participation

DEP will publish notice of the receipt of the NPDES permit application and a tentative decision to issue the individual NPDES permit in the *Pennsylvania Bulletin* in accordance with 25 Pa. Code § 92a.82. Upon publication in the *Pennsylvania Bulletin*, DEP will accept written comments from interested persons for a 30-day period (which may be extended for one additional 15-day period at DEP's discretion), which will be considered in making a final decision on the application. Any person may request or petition for a public hearing with respect to the application. A public hearing may be held if DEP determines that there is significant public interest in holding a hearing. If a hearing is held, notice of the hearing will be published in the *Pennsylvania*

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Bulletin at least 30 days prior to the hearing and in at least one newspaper of general circulation within the geographical area of the discharge.

Discharge, Receiving Waters and Water Supply Information

Outfall No.	001	Design Flow (MGD)	0.55
Latitude	41º 5' 37.0"	Longitude	-75º 19' 12.4"
Quad Name	Mount Pocono	Quad Code	1043
Wastewater Description:	IW Process Effluent with ELG		

Receiving Waters	Swiftwater Creek	Stream Code	4954
NHD Com ID	26158338	RMI	3.5
Drainage Area	6.89 mi^2	Yield (cfs/mi^2)	0.62
Q_{7-10} Flow (cfs)	4.27	Q_{7-10} Basis	Previous renewals
Elevation (ft)	1,100	Slope (ft/ft)	0.018
Watershed No.	1-E	Chapter 93 Class.	HQ-CWF, MF
Existing Use	-	Existing Use Qualifier	-
Exceptions to Use	-	Exceptions to Criteria	-
Assessment Status	Attaining Use(s)		
Cause(s) of Impairment	-		
Source(s) of Impairment	-		
TMDL Status	-	Name	-

Background/Ambient Data		Data Source
pH (SU)	-	-
Temperature (°F)	-	-
Hardness (mg/L)	-	-
Other:	-	-

Nearest Downstream Public Water Supply Intake	Brodhead Creek Regional Authority		
PWS Waters	Brodhead Creek	Flow at Intake (cfs)	13.6 (StreamStats estimate)
PWS RMI	~7.4	Distance from Outfall (mi)	~12