



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1600 John F Kennedy Boulevard
Four Penn Center
Philadelphia, Pennsylvania 19103

Report Title: Clean Water Act Compliance Inspection Report
Inspection Date(s): 07/28/2022
Regulatory Program(s): National Pollutant Discharge Elimination System (NPDES)
Type of Activity: Pretreatment – Industrial User Inspection
Facility Name: Johnson & Johnson
Permittee(s): Johnson & Johnson
Facility Operator: Johnson & Johnson
Facility Address: 400 West Lincoln Avenue, Lititz, PA 17543
Lat/Long: 40.159008/-76.3164
County/Parish: Lancaster
Permit Number: PAP120320
NAICS & SIC Codes: 325412/2834
Unique Project #: 3E22WN025A

Facility Representative(s):	Point of Contact
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Table of Contents

I. Introduction	3
A. Inspection Opening Conference	3
B. Weather and Precipitation Conditions.....	3
II. Facility Activity/Walkthrough	3
III. Observations	5
IV. Records Review	10
V. Closing Conference.....	10
VI. List of Attachments.....	10

I. Introduction

On July 28, 2022, Aaron Thomson (hereinafter, “Inspector Thomson”, “EPA Inspector”) an inspector from the U.S. Environmental Protection Agency (“EPA”) Region III conducted an on-site inspection of the Johnson and Johnson facility (hereinafter, “JNJ, “the facility”)’s pretreatment program. The facility is a manufacturing plant, producing health care products such as mouth wash and skin creams. The facility is located at 400 W Lincoln Ave, Lititz, PA 17543. JNJ is permitted by Lititz Borough to discharge into the sewage system leading to the treatment plant (**Attachment 1**). The purpose of the inspection was to observe the program’s compliance with the Clean Water Act (CWA) and the applicable Federal Pretreatment Regulations. The Pennsylvania Department of Environmental Protection was invited to the inspection but chose not to attend.

A. Inspection Opening Conference

The EPA Inspector arrived at the facility at est. 11:00 AM for the on-site inspection. Inspector Thomson met with the following facility representatives:

Table 1: Inspection Attendee List

Name	Affiliation	Telephone	Email
EPA Region III Inspectors and Contractors			
Aaron Thomson	EPA - Philadelphia	215-814-2116	Thomson.aaron@epa.gov
Site/Facility Representatives			
Brett Chronister	JNJ	(717) 626-2011	bchronis@its.jnj.com
Katherine Miller	JNJ	(717) 626-2011	kmille24@its.jnj.com

Inspector Thomson displayed his credentials to Ms. Miller and Mr. Chronister at the outset of the inspection, and explained the purpose of the inspection was to observe compliance with the Federal Pretreatment Regulations. The EPA Inspection Team informed Ms. Miller 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 Conditions

During the inspection, the weather was sunny with a high of 90 degrees Fahrenheit.

II. Facility Activity/Walkthrough

The facility is classified as a Categorical Industrial User (CIU), which is subject to the Federal Pretreatment Regulations 40 CFR Part 403 and Categorical Industrial User Regulations 40 CFR Part 439.46. The facility discharges to the Lititz Borough publicly owned treatment works (POTW). Because the facility discharges into a POTW without an approved pretreatment program, EPA is designated as the Control Authority, and as such is the authority for inspections per 40 CFR Part 403.3(f).

The Johnson and Johnson Lititz facility is a health care product manufacturing plant, with both a personal care line (skin creams) and an oral care line (mouth wash). According to Mr. Chronister, The facility employs approximately 500 employees over 6 different shifts, operating 24 hours a day with 2-10 operational engineers monitoring systems including the pretreatment system.

The facility’s manufacturing processes that contribute to the wastewater stream discharged to the sewage system includes process generated wastewater and collected overflow from both the skin cream and mouth wash production lines. Mr. Chronister stated that contained product will never be added to the wastewater

discharge stream, and “bad” batches of product would be collected and processed/recycled in-house. See below for a current schematic of the manufacturing process:

The facility’s pretreatment process receives wastewater from both skin cream and mouth wash lines, collecting and storing the wastewater in equalization tanks (EQT) 01 and 02. Wastewater from EQT01 is fed into the first neutralization tank (NT01), whereas wastewater from EQT02 will feed into EQT01 and then enter NT01. Wastewater in NT01 can feed into NT02, pH adjustment occurs in both tanks, introducing either NaOH or CO₂ to bring the pH of the wastewater within acceptable discharge limits while being continuously monitored. Once the pH is adjusted to appropriate levels, the wastewater is discharged to the sewage system leading to Lititz Borough wastewater treatment plant. See below for a current schematic of the pretreatment process:

Wastewater Equalization Facility

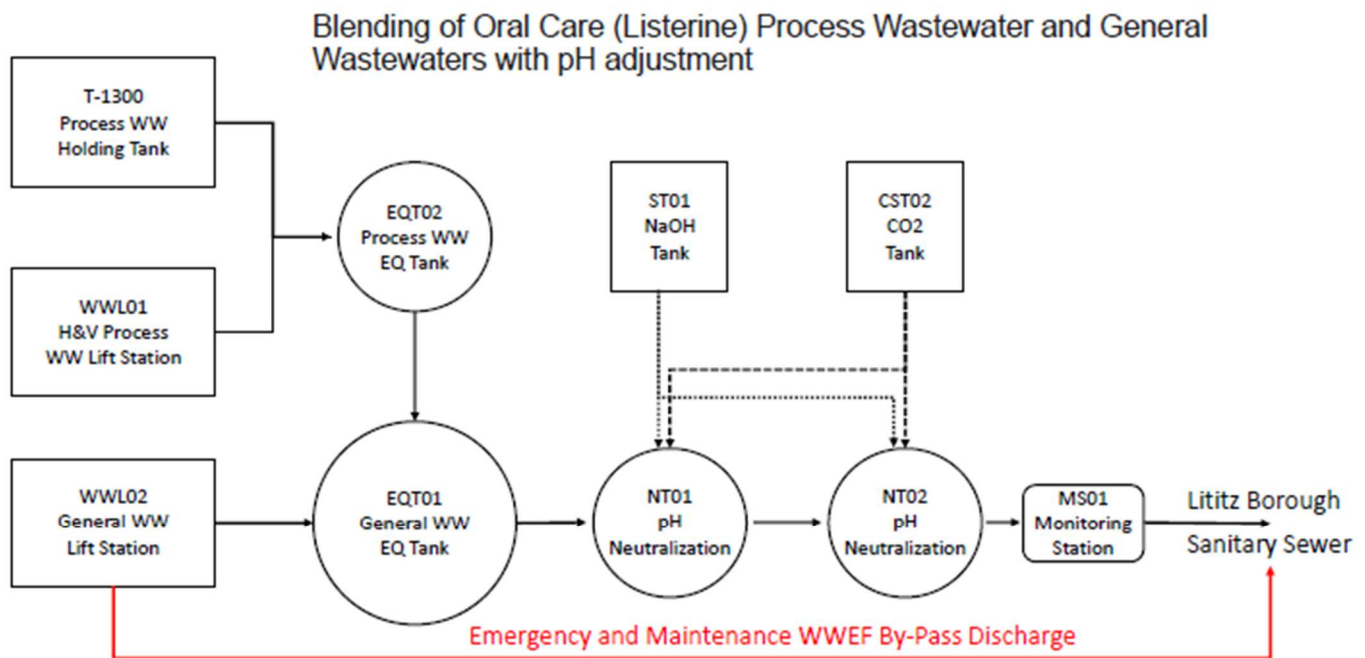


Figure 1: Schematic of pretreatment process at the time of the inspection.

After the opening conference, the facility’s staff led a tour of their pre-treatment process. First, Inspector Thomson was led to the facility’s chemical unloading/receiving sites (**Attachment 2 Photograph 1**), equipped with troughs to collect any spillage. Next, Inspector Thomson was led to the pump system (**Attachment 2 Photograph 2**) used to inject NaOH and CO₂ into the neutralization tanks (**Attachment 2 Photograph 3**). Located immediately after the neutralization tanks, Inspector Thomson was then led to the facility’s sampling/monitoring station (**Attachment 2 Photograph 4**) with a composite sampler (**Attachment 2 Photograph 5**) and discharge point/sump (**Attachment 2 Photograph 6**). Inspector Thomson was then led to the equalization tanks (**Attachment 2 Photographs 6 and 7**), which receive wastewater from various plant

processes before the wastewater stream enters the neutralization tanks for treatment. Inspector Thomson asked to see the sampling location and was led back to the monitoring station (**Attachment 2 Photograph 8**). This concluded the site tour.

III. Observations

A checklist was utilized during the review and is provided below. The checklist is divided into sections, with Observations listed under each section. Photographs were taken during the inspection by Inspector Aaron Thomson, and are provided in **Attachment 2**. Not all photographs taken during the inspection are included in this report.

Visual Observations pertaining to each section are listed at the end of each section.

Section 1.				
General Information				
	Yes	No	N/A	Comments
General Description of Processes and Products	Skin cream/Mouth wash production			
Are there any alternates to effluent monitoring conducted? (e.g., TTO/TOMP, Waiver requirements?) Describe in comments if "yes"	☐	☐	☒	
Provide production rates for all processes subject to production based standards and include:				
1) Process				
2) production rate used for calculating limits				
3) production rate for last 12 months				
Any anticipated changes in processes or production rates?	☐	☐	☒	
List the production rate listed on the approval letter				
Shift information, list	500 employees, 6 shifts, 24/7 operation, 2-10 operation engineers on floor monitoring systems (such as pretreatment) at all times			
1) Shift #				
2) No. of Employees				
3) Hours				
4) Work Days				
Is production seasonal? If yes, describe	☐	☐	☐	
List all visual observations pertaining to this section				

Section 2.				
Categorical Industry				
	Yes	No	N/A	Comments
Categorical Industry?	☒	☐	☐	
Category(s):	40 CFR Part 439.46,			
Subcategory(s):	Subpart D: Mixing/Compounding and Formulation.			
Regulatory New Source Date:				

07/28/2022

New source?	☐	☒	☐	
List of categorical processes	Skin cream/mouth wash production			
List of other operations producing wastewater	n/a (from overflow of production)			
List all visual observations pertaining to this section				

Section 3.				
Characterization of Wastewater Discharges (CFR ##.##.##)				
	Yes	No	N/A	Comments
Describe the time of day discharge to sewer occurs	Continuously			
Are discharges seasonal (if yes, describe)	☐	☒	☐	
Attach a block flow diagram of manufacturing process in the Facility Activity section of the inspection report, including: chemical storage area, and wastewater generated. Identify all regulated, unregulated and dillution wastewater discharges. Include sample location, discharge flow rates and method of disposal*. Note any recent changes. *disposal method CD - Continuous discharge to sanitary ND - Not discharged or disposed BD - Batch discharge to sanitary sewer HH - Hauled as hazardous waste OD - Other disposal - not to sanitary sewer HW - Hauled as nonhazardous waste				
List all visual observations pertaining to this section				
Per permit, various parameters (Zinc, Copper, pH, Fats, Oils & Grease, Biochemical Oxygen Demand (BOD), ammonia (NH3-N), Total Phosphorus (TP) and Total Suspended Solids (TSS)) have permitted deviations to the local limits based on the POTW's history treating their discharge (Attachment 1 Section 6 part B)				

Section 4.				
Pretreatment Facility				
	Yes	No	N/A	Comments
Pretreatment installed?	☒	☐	☐	
Attach a schematic of the pretreatment facility in the Facility Activity section of the inspection report (include all units and sludge storage)				
Briefly describe treatment processes and operation.				
Describe sludge storage and disposal method	Continuously monitor before discharging to prevent slugs			
Describe appearance of effluent at time of inspection.	n/a			
List all visual observations pertaining to this section				

Section 5.				
Self Monitoring				

	Yes	No	N/A	Comments
Does facility have a sampling plan or protocol including use of 40 C.F.R. Part 136 techniques (obtain copy)?	☐	☐	☒	Sampling performed by ALS Environmental
Is sampling location (identified on block flow diagram) the same as in control mechanism? If no, explain.	☒	☐	☐	
Is this sampling location permanently identified by a sign, painted number, or other means?	☒	☐	☐	Attachment 2 Photograph 4
Is this sampling location appropriate? If no, explain...	☒	☐	☐	
Is this sampling location shown on the chain of custody form?	☒	☐	☐	Chain of Custody (CoC)
Are any parameters monitored by approved methods more frequently than required at permitted sampling location?.	☐	☒	☐	
If yes to previous question, are all results submitted to the control authority?	☒	☐	☐	If they were sampled above frequency, all would be reported
Does facility resample and report within 30 days of discovering a violation?	☒	☐	☐	
Are sampling records maintained on site? Describe for how long.	☒	☐	☐	3 years+
Is flow determined as required by permit?	☒	☐	☐	
How is flow determined (i.e., estimated or measured)?	Measured continuously (meter)			
Is flow measurement appropriate?	☒	☐	☐	
Is flow measurement device calibrated?	☒	☐	☐	Calibrated by Hawk calibration Services at least annually
Does the facility have an operator's manual for its pH meters?	☒	☐	☐	
Does the facility do a proper 2-point calibration of its pH meter in accordance with the operator's manual?	☐	☐	☒	
Is other monitoring equipment (e.g. DO meter) calibrated? Describe how often if yes.	☐	☐	☒	
Is sampling and analysis done in-house or by contract? If by contract, list company.	☐	☐	☐	Contract, ALS environmental
Is QA/QC program for sampling and analysis adequate? Obtain copy of plan if available.	☐	☐	☒	ALS
List all visual observations pertaining to this section	Per permit, various parameters have permitted deviations to the local limits based on the POTW's history treating their discharge (Attachment 1 Section 6 part B)			

Section 6.				
Hazardous Waste Management				
	Yes	No	N/A	Comments

Is IU aware of RCRA regulations?	☒	☐	☐	
Does facility generate any hazardous waste? If yes, indicate type of waste, method of management on site and means of disposal on a separate sheet. Describe any spillage problems or any other releases that are observed.	☐	☐	☒	Outside of scope
Has facility notified POTW and EPA of any hazardous waste discharges to the sewer?	☐	☒	☐	
List all visual observations pertaining to this section				

Section 7.				
Spill Prevention				
	Yes	No	N/A	Comments
Has the facility had any spills or been responsible for slug loads? List dates of events in comments.	☐	☒	☐	
If yes to previous question, was POTW notified?	☐	☐	☒	
Does the facility have spill notification procedures posted?	☒	☐	☐	
Has the facility evaluated its need for a spill prevention plan at least every two years?	☒	☐	☐	
If yes to previous question, was it determined that they needed one?	☒	☐	☐	Attachment 4
Does the IU have a spill prevention (SP) plan to address spills to the POTW?	☒	☐	☐	
If spills occurred- Did the IU follow procedures outlined in the spill plan at the time of spills?	☐	☐	☒	
If spills occurred- Were procedures effective in containing the spill?	☐	☐	☒	
Is the facility keeping records of spill events?	☐	☐	☒	
Have there been any changes in spill procedures recently. Describe if yes.	☐	☒	☐	
List all visual observations pertaining to this section				

Section 8.				
Recordkeeping Review.				
	Yes	No	N/A	Comments
Current IU control mechanism (through EPA, not a permit)	Attachment 1			
Notices and correspondence with control authority including:				
a. Self monitoring report transmittals?	☒	☐	☐	Self monitoring reports (Attachment 3) received by facility from ALS are sent control authority
b. BMR if required?	☐	☐	☒	
c. Other?	☐	☐	☐	

Do sampling records include:				
a. Date of sampling event?	☒	☐	☐	Chain of Custody (Attachment 3)
b. Time of sampling event?	☒	☐	☐	CoC 3
c. Name of sampling person and affiliation?	☒	☐	☐	CoC 3
d. Sample collection method?	☒	☐	☐	CoC 3
e. Method of sample preservation?	☒	☐	☐	CoC 3
f. Description of sample location?	☒	☐	☐	CoC 3
g. Name of person conducting analysis?	☒	☐	☐	CoC 3
h. Date of analysis?	☒	☐	☐	CoC 3
i. Time of analysis, if applicable (i.e., BOD, Cr?)	☒	☐	☐	CoC 3
j. Sample analysis method?	☒	☐	☐	CoC shows requested method, analysis results (Attachment 3) show method used
Is type of sample specified in control mechanism?	☒	☐	☐	CoC 3
Are all parameters monitored at the required frequency? Note any discrepancies in comments.	☒	☐	☐	
Analytical results?	☒	☐	☐	Analysis 9 (Attachment 3)
Are all monitoring results sent to the Control Authority?	☒	☐	☐	
Are copies sent to the POTW?	☒	☐	☐	
Appropriate production records for production based standards?	☐	☐	☒	
Documentation of flow rates and volumes?	☒	☐	☐	
Are records maintained at least 3 years?	☒	☐	☐	
List all visual observations pertaining to this section				

Section 9.				
EPA Sampling				
	Yes	No	N/A	Comments
Were samples taken?	☐	☒	☐	
Describe sampling location, method, and time:				
List all visual observations pertaining to this section				

Section 10.				
Stormwater				
	Yes	No	N/A	Comments
Does facility have a stormwater permit?	☐	☐	☒	
If yes, describe what type of permit along with issuance and expiration dates	Outside of scope			

07/28/2022

Does facility have a stormwater pollution prevention plan?	☐	☐	☒	
Describe any BMPs that the facility is currently implementing.				
List all visual observations pertaining to this section				

Section 11.				
Current Compliance Status				
	Yes	No	N/A	Comments
Indicate compliance with:				
a. effluent limits (indicate in comments the date range reviewed)	☒	☐	☐	
b. monitoring (indicate in comments the date range reviewed)	☒	☐	☐	
c. recordkeeping/reporting (indicate in comments the date range and records reviewed)	☒	☐	☐	
List all visual observations pertaining to this section				

IV. Records Review

As part of the inspection, Inspector Thomson requested the following documentation be sent via email up to two weeks after the inspection: Control mechanism, categorical status, 2 years worth of monitoring reports, slug/spill prevention plan and process flow diagrams relating to the pretreatment system. Ms. Miller sent requested control mechanism and monitoring reports via email on 7/28/22 and 8/15/22 and Mr. Groft sent the requested categorical status, process diagram and spill prevention plan on 9/14/22. Records relevant to the inspection report are attached.

V. Closing Conference

After the facility inspection, the EPA Inspection Team met with the facility representatives for a closing conference. The EPA Inspection Team shared 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 reviewed additional materials following the inspection.

The inspection concluded at 2:30 PM

VI. List of Attachments

- Attachment 1.** JJ Discharge Agreement - Signed
- Attachment 2.** Photo Log
- Attachment 3.** 45 Monitoring Reports
- Attachment 4.** Accidental Slug Prevention and Control Plan (Rev 3) 8-5-19
- Attachment 5.** Wastewater EQ Facility General Flow Diagram