NORTH CAROLINA DIVISION OF AIR QUALITY

Application Review

Issue Date: DRAFT

Region: Raleigh Regional Office
County: Wake
NC Facility ID: 9200349
Inspector's Name: Dawn Reddix
Date of Last Inspection: 03/22/2023
Compliance Code: 3 / Compliance - inspection

Facility Data

Applicant (Facility's Name): SpecGx LLC - Mallinckrodt Pharmaceuticals

Facility Address:
SpecGx LLC - Mallinckrodt Pharmaceuticals
8801 Capital Boulevard
Raleigh, NC 27616

SIC: 2833 / Medicinals and Botanicals
NAICS: 325411 / Medicinal and Botanical Manufacturing

Facility Classification: Before: Title V **After:** Title V
Fee Classification: Before: Title V **After:** Title V

Permit Applicability (this application only)

SIP: 02D .0524 and .1806
NSPS: Subparts NNN, RRR, and VVa
NESHAP: EEE
PSD: N/A
PSD Avoidance: N/A
NC Toxics: 02D .1100 and 02Q .0711
112(r): N/A
Other: N/A

Contact Data

Facility Contact	Authorized Contact	Technical Contact
Timothy Roberts Principal Environmental Engineer (919) 878-2895 8801 Capital Boulevard Raleigh, NC 27616	David Phillips Site Director (919) 878-4733 8801 Capital Boulevard Raleigh, NC 27616	Timothy Roberts Principal Environmental Engineer (919) 878-2895 8801 Capital Boulevard Raleigh, NC 27616

Application Data

Application Number: 9200349.24A
Date Received: 06/12/2024
Application Type: Modification
Application Schedule: TV-Sign-501(b)(2) Part II

Existing Permit Data
Existing Permit Number: 01479/T63
Existing Permit Issue Date: 08/16/2023
Existing Permit Expiration Date: 07/31/2025

Total Actual emissions in TONS/YEAR:

CY	SO2	NOX	VOC	CO	PM10	Total HAP	Largest HAP
2022	14.47	48.76	21.51	27.98	9.74	8.41	4.12 [Aniline]
2021	15.45	52.51	20.82	25.84	9.64	7.69	3.93 [Aniline]
2020	16.08	54.08	20.57	33.50	9.58	8.57	4.63 [Aniline]
2019	14.69	47.43	19.99	26.36	8.91	8.07	3.88 [Aniline]
2018	14.23	44.56	18.82	28.37	9.43	7.92	3.66 [Aniline]

Review Engineer: Connie Horne

Review Engineer's Signature: **Date:** DRAFT

Comments / Recommendations:
Issue 01479/T64
Permit Issue Date: DRAFT
Permit Expiration Date: July 31, 2025

1. Purpose of Application

This permit action is for Part II of a two-step process allowed under 15A NCAC 02Q .0501(b)(2). The Rule states:

(c) With the exception in Paragraph (d) of this Rule, the owner or operator of an existing facility, new facility, or modification of an existing facility (except for minor modifications under Rule .0515 of this Section), including significant modifications that would not contravene or conflict with a condition in the existing permit, subject to the requirements of this Section shall not begin construction without first obtaining:

(1) a construction and operation permit following the procedures under this Section (except for Rule .0504), or
(2) a construction and operation permit following the procedures under Rule .0504 and filing a complete application within 12 months after commencing operation to modify the construction and operation permit to meet the requirements of this Section.

The Permittee submitted an application for a significant 501(b)(2) Part I permit (9200349.20B) on December 21, 2020. The Part I permit was issued on June 14, 2023 and included the following approved permit modifications made to both PAP manufacturing plants (Plant 201 and 205):

- Add and modify the equipment in the PAP manufacturing plants to increase the output by approximately 15 percent.
- Revise the feed rates and operational limits for existing hazardous waste combustors as per the recent testing.
- Revise the currently approved air toxics emissions limits based on the new modeling analysis.
- Include applicability of NSPS Subparts RRR and VVa for new reactors and modified equipment for the PAP plant.

On June 12, 2024, DAQ received this Part II application (9200349.24A) from SpecGx LLC – Mallinckrodt Pharmaceuticals to complete the process to include the above-listed changes as required in condition 2.2 B.1.a of Permit 01479T62. This application was received within the 12-months after the issuance of the Part I permit on June 29, 2023, therefore, this application was received within the required timeframe. The technical review for the Part I application (9200349.20B) is attached to this document.

2. Facility Description

The Mallinckrodt plant produces para-aminophenol (PAP) and acetyl-para-aminophenol (APAP, commonly called acetaminophen) as primary products. Currently, it manufactures the majority of the US supply of acetaminophen. These manufacturing processes are located in separate buildings on the premises, occurring as separate manufacturing processes. PAP is produced on site as an intermediate product that is subsequently used in the production of APAP. At the same time, the PAP process produces aniline as a co-product. In the APAP process, PAP is used with acetic anhydride in a chemical process unit that produces and purifies APAP. In addition to producing APAP, acetic acid is separated from the process liquors as a by-product of the process. Emission sources from PAP and APAP primarily consist of reactors, process vessels, storage tanks, transfer racks, dryers, product sizing equipment, and leaks from process line components and connectors such as valves, flanges, pumps, agitators, and safety devices. Thermal energy for the manufacturing processes is supplied from four boilers located on site. The pharmaceutical plant also has a wastewater treatment process for pre-treating its process effluent prior to discharging to the City of Raleigh's POTW (Publicly Owned Treatment Works).

3. Application Chronology

June 12, 2024	Part II application received.
June 26, 2024	Sent acknowledgment letter. Application complete.
August 15, 2024	Draft to applicant and regional office
August 13, 2024	Draft to public notice and EPA
September 14, 2024	Public comment period ends
September 29, 2024	EPA Comment period ends
DRAFT	Permit issued

4. Permit Modifications/Changes

The table below outlines the proposed changes to the current permit (01479T63):*

Page No.	Section	Description of Changes
Cover Letter	---	Modified to reflect current permit number, issue and effective dates
All	Headers	Amended permit revision number
1-44	Entire permit, where applicable	Modified to reflect current permit number, issue and effective dates
4-6	Section 1 Equipment Table	Removed footnote regarding requirement to file application within one year from the issuance of Air Quality Permit 01479T62 and asterisks for emission sources PAP-1, PAP-6, PAP-22, PAP-23, BH-900 and ES Fugitives
34	2.2 B	Removed "15A NCAC 02Q .0504: OPTION FOR OBTAINING CONSTRUCTION AND OPERATION PERMIT". This requirement was satisfied with the application (.24A) received June 12, 2024
37-44	Section 4	Updated General Conditions from version 6.0 (01/07/22) to version 8.0 (07/10/2024)

* This list is not intended to be a detailed record of every change made to the permit but a summary of those changes.

5. General Condition J Removed from Permit (see discussion below)

EPA has promulgated a rule (88 FR 47029, July 21, 2023), with an effective date of August 21, 2023, removing the emergency affirmative defense provisions in operating permits programs, codified in both 40 CFR 70.6(g) and 71.6(g). EPA has concluded that these provisions are inconsistent with the EPA's current interpretation of the enforcement structure of the CAA, in light of prior court decisions[1]. Moreover, per EPA, the removal of these provisions is also consistent with other recent EPA actions involving affirmative defenses[2] and will harmonize the EPA's treatment of affirmative defenses across different CAA programs.

As a consequence of this EPA action to remove these provisions from 40 CFR 70.6(g), it will be necessary for states and local agencies that have adopted similar affirmative defense provisions in their Part 70 operating permit programs to revise their Part 70 programs (regulations) to remove these provisions. In addition, individual operating permits that contain Title V affirmative defenses based on 40 CFR 70.6(g) or similar state regulations will need to be revised.

Regarding NCDAQ, it has not adopted these discretionary affirmative defense provisions in its Title V regulations (15A NCAC 02Q .0500). Instead, DAQ has chosen to include them directly in individual Title V permits as General Condition (GC) J.

Per EPA, DAQ is required to promptly remove such impermissible provisions, as stated above, from individual Title V permits, after August 21, 2023, through normal course of permit issuance.

6. Other Requirements

- An application fee of $1002 was required for this application and was received on 6/12/24.
- The appropriate number of application copies were received on 6/12/24.
- The application was signed by Mr. David Phillips, Site Director, on 6/11/24 as the Responsible Official.
- Wake County has triggered increment tracking under PSD for SO_2. Any increment changes associated with this modification were addressed in the Part I permit (No. 01479T62).
- The associated dates are listed in the Application Chronology section above.

7. Public Notice

Public notice and EPA review is required for the completion of this two-step significant process. A notice of the DRAFT Title V Permit shall be made pursuant to 15A NCAC 02Q .0521. The notice will provide for a 30-day

comment period, with an opportunity for a public hearing. Copies of the public notice shall be sent to persons on the Title V mailing list and EPA. Pursuant to 15A NCAC 02Q .0522, a copy of each permit application, each proposed permit and each final permit shall be provided to EPA. Also, pursuant to 15A NCAC 02Q .0522, a notice of the DRAFT Title V Permit shall be provided to each affected State at or before the time notice is provided to the public under 15A NCAC 02Q .0521, above.

8. Facility Compliance Status

This facility was last inspected on March 22, 2023 by Dawn Reddix of the Raleigh Regional Office. According to Ms. Reddix's report, this facility appeared to operate in compliance with the applicable air quality regulations and permit conditions at the time of the inspection.

9. Conclusions, Comments and Recommendations

The issuance of Air Quality Permit No. 01479T64 to SpecGx LLC - Mallinckrodt Pharmaceuticals is recommended.

ATTACHMENT

Technical Review for Part I
Permit Application No. 9200349.20B

NORTH CAROLINA DIVISION OF AIR QUALITY

Application Review

Issue Date: June 14, 2023

Region: Raleigh Regional Office
County: Wake
NC Facility ID: 9200349
Inspector's Name: Dawn Reddix
Date of Last Inspection: 07/21/2021
Compliance Code: 3 / Compliance - inspection

Facility Data

Applicant (Facility's Name): SpecGx LLC - Mallinckrodt Pharmaceuticals

Facility Address:
SpecGx LLC - Mallinckrodt Pharmaceuticals
8801 Capital Boulevard
Raleigh, NC 27616

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Permit Applicability (this application only)

SIP: 02D .0524 and .1806
NSPS: Subparts NNN, RRR, and VVa
NESHAP: EEE
PSD: N/A
PSD Avoidance: N/A
NC Toxics: 02D .1100 and 02Q .0711
112(r): N/A
Other: N/A

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Application Data

Application Number: 9200349.20B
Date Received: 12/21/2020
Application Type: Modification
Application Schedule: TV-Sign-501(b)(2) Part I

Existing Permit Data
Existing Permit Number: 01479/T61
Existing Permit Issue Date: 4/4/2022
Existing Permit Expiration Date: 07/31/2025

Total Actual emissions in TONS/YEAR:

CY	SO2	NOX	VOC	CO	PM10	Total HAP	Largest HAP
2020	16.08	54.08	20.57	33.50	9.58	8.57	4.63 [Aniline]
2019	14.69	47.43	19.99	26.36	8.91	8.07	3.88 [Aniline]
2018	14.23	44.56	18.82	28.37	9.43	7.92	3.66 [Aniline]
2017	13.84	42.47	18.56	30.63	10.39	8.61	3.61 [Aniline]
2016	12.19	40.72	17.52	26.01	9.78	7.69	3.55 [Aniline]

Review Engineer: Rahul Thaker

Review Engineer's Signature: **Date:** June 14, 2023

Comments / Recommendations:
Issue 01479/T62
Permit Issue Date: June 14, 2023
Permit Expiration Date: July 31, 2025

1. Purpose of Application

SpecGx LLC - Mallinckrodt Pharmaceuticals (Mallinckrodt), submitted a 1st step application under the "two-step" significant modification procedure, pursuant to 15A NCAC 02Q .0501(b)(2), requiring this application to be processed as a 02Q .0300 modification to its current Title V permit. The changes included in the application are discussed in Section 5.1 below.

2. Application Chronology

December 21, 2020	Application received and deemed it "complete" effective this day.
October 21, 2021	Application reassigned to Rahul Thaker (from the former employee Kevin Godwin).
November 12, 2021	Emailed the applicant consultant to provide emissions calculations spreadsheet and Word copy of the application.
November 15, 2021	Requested information received.
February 23, 2022	Took an initial look at the application and emailed the consultant for a need for conference call to discuss the application content.
March 3 and 4, 2022	Discussed issues on applicability for various NSPSs, NESHAPSs, and PSD, and emissions calculations and their basis. Requested information on (i) design capacities for the facility for both before and after modification for both PAP and APAP production, (ii) certification on emissions of 1-bromopropane, (iii) facility wide actual and potential emissions of PM10, PM2.5, lead, and individual HAPs, (iv) NSPS RRR notification providing TRE evaluation, and (v) applicability of NESHAP VVVVVV.
July 12, 2022	Asked for information on pre-project emissions, TRE index value calculations, zoning determination, applicability of NSPS VV v. VVa, and state-regulated air toxics.
November 2, 2022	Received information on most of the issues.
December 29, 2022	Emailed the applicant that their responses on PSD and air toxics issues were not adequate.
January 5, 2023	Emphasized to the applicant that the correct applicability test under PSD (actual-to-projected actual or actual-to-potential) need to be used for the modification including the emissions of debottlenecked units, and need for compliance with 02D .1100 for ammonia emissions.
March 24, 2023	Received the PSD applicability and revised modeling for ammonia.

3. Statement of Compliance

Dawn Reddix of Raleigh Regional Office conducted a compliance inspection on September 15, 2022. She concluded that "based on observations made during this inspection, Mallinckrodt's Raleigh plant appeared to be operating in compliance with all permit requirements."

Separately, DAQ issued a notice of violation (NOV) on April 21, 2021 for construction and operation of several pieces of equipment (total 13 for para-amino phenol plant) without obtaining an air permit. The agency received a response on this NOV on May 13, 2021 and deemed the matter resolved. Specifically, the Permittee applied for a permit for these previously constructed sources on December 20, 2020.

With regard to the submitted application, the responsible official certified that the facility was in non-compliance with the applicable requirements in NSPS Subparts RRR and VVa through completion of E5 and E4 forms. The facility provided a narrative on how it intended to achieve compliance with these applicable requirements, which are discussed in Section 5.3 below. It is noted that the applicant had completed the start-up notifications (both commence construction and start-up for both NSPSs (New Source Performance Standards) Subparts RRR and VVa on December 22, 2020. In addition, it is DAQ's understanding that semi-annual reports for both NSPS Subpart RRR and VVa are also being submitted. Finally, issuance of this permit revision will bring the facility back in compliance for the previously unpermitted equipment, discussed in Section 5.1 below.

4. Facility Operations

The Mallinckrodt plant produces para-aminophenol (PAP) and acetyl-para-aminophenol (APAP, commonly called acetaminophen) as primary products. Currently, it manufactures the majority of the U.S. supply of acetaminophen.

These manufacturing processes are located in separate buildings on the premises, occurring as separate manufacturing processes. PAP is produced on site as an intermediate product that is subsequently used in the production of APAP. At the same time, the PAP process produces aniline as a co-product. In the APAP process, PAP is used with acetic anhydride in a chemical process unit that produces and purifies APAP. In addition to producing APAP, acetic acid is separated from the process liquors as a by-product of the process. Emission sources from PAP and APAP primarily consist of reactors, process vessels, storage tanks, transfer racks, dryers, product sizing equipment, and leaks from process line components and connectors such as valves, flanges, pumps, agitators, and safety devices. Thermal energy for the manufacturing processes is supplied from four boilers located on site. The pharmaceutical plant also has a wastewater treatment process for pre-treating its process effluent prior to discharging to the City of Raleigh's POTW (Publicly Owned Treatment Works).

5. Proposed Modifications

5.1 Project Description

Production of APAP of the facility is limited by the PAP production capacity which is the bottleneck for the facility. Mallinckrodt has recently experienced increased demand internationally for its acetaminophen and now a specific new demand due to domestically manufactured acetaminophen due to COVID-19. Therefore, the facility needs to increase the PAP output in order to meet the additional domestic and international acetaminophen demand.

There are two PAP manufacturing plants (Plant 201 and 205) at the facility. Modifications were made to both plants to increase PAP output.

PAP is produced by a continuous catalytic reaction process where liquid nitrobenzene is hydrogenated and acidified by sulfuric acid to form PAP sulfate and aniline sulfate. These products are then converted to PAP and aniline by neutralization with ammonia to precipitate tars. The final PAP mixture is washed with aniline, crystallized, and separated physically by centrifugation before vacuum drying. Throughout the process, distillation and extraction units are used to recover spent solvent and separate PAP from by-products such as aniline, ammonium sulfate, and aniline tar. Plants 201 and 205 share an organic recovery unit and an aqueous recovery unit.

Process vents from the hydrogenation processes in plants 201 and 205 are vented to the dedicated flash arrestor tanks (safety devices) prior to being vented to respective nitrobenzene recovery absorbers. Process vents from the neutralization, crystallization, and drying processes from both plants plus organic and aqueous recovery are vented to a single packed bed scrubber (PAPSCRUB - SCR-2022). K083 tar is a waste by-product of the reaction and is used for fuel in boilers No. 2 & 7 (BH-2 & BH-7).

The application includes "Confidential" equipment lists for all equipment in both PAP plants 201 and 205. All hydrogenation reactors for Plant 201 are listed under emission source PAP-1. All hydrogenation reactors for Plant 205 are listed under emission source PAP-6. The equipment for the PAP crystallization reactors are listed under PAP-22 for Plant 201 and PAP-23 for PAP 205. The vents for the crystallizers from each plant are directed to a common scrubber (PAPSCRUB) for ammonia and nitrobenzene removal.

The following Table lists all new equipment which have been added or modified as part of the proposed project:

Equipment Name	Equipment ID	Description	Date Operation Began	Emission Point
Building 201				
Pressure Seal Pot	T-0240	Replaced/new design	10/11/2019	PAP-1 - Flash Arrestor Tank (T-226) and scrubber (SC-2007)
Hydrogenation Decanter	T-0241	Replaced/new design	10/11/2019	
Organic Seal Pot	T-0242	Replaced	10/11/2019	
Aqueous Seal Pot	T-0206	Replaced/new design	3/16/2017	
Nitrobenzene Stripper Reboiler	TBD	Replaced/bigger design	TBD	

Equipment Name	Equipment ID	Description	Date Operation Began	Emission Point
pH Tank No. 1 (with vacuum condenser)	T-0282	New	2/13/2020	PAP 22 - House condenser (HE-239) and house scrubber (SCR-2022)
Catch Pot and Condenser	T-2282	New	1/13/2020	
Building 205				
Hydrogenation Reactor No. 6	T-0327	New	8/27/2019	PAP-6 - Flash Arrestor Tank (T-311) and scrubber (SC-3006)
Pressure Seal Pot	T-0329	Replaced	5/21/2019	
Nitrobenzene Stripper Reboiler	TBD	Replaced/bigger design	TBD	
pH Tank No. 1 (with vacuum condenser)	T-0363	New	1/8/2020	PAP 23 - House condenser (HE-292) and house scrubber (SCR-2022)
Catch Pot and Condenser	T-3633	New	12/4/2019	
Centrate Decanter (with Weir Pot)	T-0324 (w/ T-0325)	Replacing/new design	TBD	

Thus, the Permittee submitted the application for the following changes:

(i) Add and modify the equipment in the PAP manufacturing plants to increase the output by approximately 15 percent.

(ii) Revise the feed rates and operational limits for existing hazardous waste combustors as per the recent testing.

(iii) Revise the currently approved air toxics emissions limits based on the new modeling analysis.

(iv) Include applicability of NSPS Subparts RRR and VVa for new reactors and modified equipment for the PAP plant.

5.2 Project Emissions

Pollutant emissions from the PAP plants include particulate matter (PM), sulfur dioxide (SO_2), volatile organic compounds (VOC), nitrobenzene, benzene, ammonia, and aniline. Emissions occur at the following locations:

1. PAP- 1 (T-226) - flash arrestor tank building 201
2. PAP-6 (T-311) - flash arrestor tank building 205
3. PAP-2 PAP vacuum pumps building 201
4. PAP-7 PAP vacuum pumps building 205
5. PAP-11 - Nitrobenzene rail/truck unloading
6. PAP-12 - Bulk nitrobenzene storage tank
7. PAP-22 - house condenser (HE-239) and PAP scrubber (SCR-2022) - building 201
8. PAP-23 - house condenser (HE-292) and PAP scrubber (SCR-2022) - building 205
9. Fugitive emissions from PAP plant (PAP-18, 19, & 20)
10. PAP-8 - Bulk bagging and packaging (BB-3045)
11. PAP-10 - Aniline Bulk Storage Tank
12. PAP-25T & R - Aniline Loading

The following sections discuss the methodology used to estimate actual and potential emissions from each source.

Flash Arrestor Tanks (PAP-1 & PAP-6)

Liquid nitrobenzene is hydrogenated and acidified in reactor vessels to produce aniline sulfate and PAP sulfate in a continuous system. Each reactor vessel is maintained under equalized pressure while hydrogen is added. A nitrogen purge of the system occurs periodically, resulting in emissions of VOC and HAPs from the reactors vessels to a flash arrestor tank. The off-gases are sent through a condenser and absorber to recover nitrobenzene. Emissions are directly dependent on the frequency of the nitrogen gas purge and the number of reactor vessels. The addition of one new reactor in PAP 205 and an increase in total throughput results in an increase in emissions.

Post-project emissions from the PAP-1 and PAP-6 were estimated using worst-case conservative purge rates, mass balance, and the methods prescribed in "Methods for Estimating Air Emissions from Chemical Manufacturing Facilities", August 2007, Volume 2, Chapter 16, RTI International Research Triangle Park, NC. VOCs, nitrobenzene, benzene, and aniline are the pollutants emitted from the process.

A water packed-bed column absorber for each plant is used to recover and recycle nitrobenzene from the purge gas back into the process. At least 99 percent of all nitrobenzene flashed into the purge gas is recovered and returned to the process. No recovery is anticipated for benzene or aniline. Mallinckrodt has historically not considered reductions in nitrobenzene emissions due to the recovery and recycling in the absorbers. Calculated post-project potential emissions are therefore lower than previously permitted.

PAP Neutralization, Crystallization, and Drying (PAP-22 & PAP-23)

PAP and aniline sulfates generated during the hydrogenation process are neutralized by the addition of ammonia to precipitate tars. The mixture is then washed with aniline in a column and further neutralized to form PAP and aniline. The PAP is crystallized and separated from the process stream by centrifugation and washed with aniline in centrifuges prior to vacuum drying. Process vents from the neutralization, crystallization, and drying processes from both plants plus organic and aqueous recovery are vented to a single packed bed scrubber (PAPSCRUB - SCR-2022).

Emissions from the neutralization and crystallization processes include VOCs, aniline, ammonia, and SO_2. Emissions of aniline, SO_2 and VOCs are estimated using emission tests completed on PAP 201 and 205 exhaust points prior to scrubbers but post house condenser in 2003. The new rates of pollutant emissions from the process are estimated to increase by 15 percent, in lockstep with the rate of increase in PAP total output. Additional estimations of ammonia exhaust from the pH and crystallization tanks were provided by the vendor and are included in Appendix 2 of the application.

Emissions from the PAP-22 and PAP-23 are controlled by the vent condensers (CD-COND-3 for PAP-22 and CD-COND-2 for PAP-23) and a common, house packed bed scrubber (CD-PAPSCRUB). The scrubber was primarily installed to control emissions of aniline and ammonia. The original design of the scrubber was over engineered to accommodate double the actual flow rate from the neutralization, crystallization, and drying processes. The additional load of pollutants anticipated due to the project will be continuing to be controlled at the original efficiencies (98 percent for ammonia and aniline).

Every two to three days the tar storage tanks T-384 and T-385 are emptied to BH-900. During the event, process lines are heated and purged. The purge gas is vented back to the house PAP scrubber (CD-PAPSCRUB). Conservative worst-case emissions from this process are estimated using historical stack test data from 2003. The duration and intensity of these events will not change; however, the frequency of empty events will increase. The purge process takes 2 to 3 hours to complete, and emissions are mostly aniline, benzene and nitrobenzene. Estimates of nitrobenzene emissions include 98 percent control from the PAP scrubber.

K-083 Tar Tank (BH-900)

This tank is an existing 10,000 gallon feed tank used to hold aniline still bottoms (RCRA waste code K083, referred herein as "K083 or "aniline tar") before it is combusted in either BH-2 or BH-7. Tar is transferred from process storage tanks in the PAP plant.

Previous emission estimates from the BH-900 assumed tar composition was approximately 18 percent aniline, 1 percent nitrobenzene, and the balance as heavy organics. However, operational variability can cause the average aniline concentration to be closer to 23 percent at times, resulting in a slight change in emissions.

The BH-900 tank is kept at 150 degrees Celsius and is sealed except when it is being filled. Potential emissions from the tank, therefore, are due to working losses only; there are no breathing losses from the tank. Volatile organic compounds (VOC) originating from the aniline tar are present in the headspace and are displaced while the tank is being filled.

Potentia1 emissions from BH-900 are quantified using the EPA's AP-42 Chapter 7.1, Organic Chemical Storage Tank, March 2020 version. The chemical properties of aniline, benzene, and nitrobenzene are available in AP-42. The heavy organic portion of the tar was assumed to exhibit properties similar to No. 6 fuel oil. It was necessary to make this approximation since the vapor pressure and density of the heavy organics fraction has not been measured. The tank is filled periodically in a batch type of operation. The frequency depends on the cycle time for the aniline still (located in the PAP plant) which produces the aniline tar. The filling time is typically 90 minutes, depending on the pumping rate and batch size. For the purposes of estimating potential emissions, a pumping rate of 90 gallons per minute is used. The vent from the tank will be configured to exhaust to Boilers No. 2 and 7, or to the atmosphere through the Boiler No. 7 stack (which will concurrently vent flue gases from Boiler No. 7 only when landfill gas or natural gas is combusted). The BH-2 and BH-7 boilers are estimated to remove at least 99.99 percent of aniline, nitrobenzene, and benzene while combusting aniline tar.

Fugitive PAP Emissions (PAP-18, PAP-19, PAP-20)

Fugitive emissions due to heavy liquid service are represented in the PAP-18, PAP-19, PAP-20 emissions sources. Fugitive VOC and HAP emissions from PAP-18, PAP-19, PAP-20 above have been historically estimated using the EPA's *Protocol for Equipment Leak Emission Estimates*, November 1995 for equipment with less than 10,000 ppmv screening values in heavy liquid service. Pollutant emission estimates are estimated based on the number of valves, pumps, agitators, and flanges. A post-project inventory of equipment was completed to determine the current number of valves, pumps agitators, and flanges. Mallinckrodt has historically estimated the breakdown between aniline and nitrobenzene in the PAP plant to be 50/50, with benzene being a very minor 0.001 percent. The project, along with previous process improvements, resulted in a net reduction of overall components (e.g., valves, pumps, flanges, and agitators), resulting in a slight decrease in fugitive emissions.

Other PAP Emission Sources

Other pollutant sources in the PAP plant include volatile emissions from storage tanks, particulate emissions from crystallized PAP, and emission losses to product transfers. Actual emissions from these sources are anticipated to increase approximately 15 percent annually. However potential emissions in the short-term (1-hour and 24-hour) and long-term (annual) will not change. Potential emission estimates from these sources are not detailed in this application and have been previously reviewed by the agency.

Utilization of the APAP plant, utilities, and hazardous waste combustors are anticipated to increase due to the PAP plant modifications. This will result in an approximate 15 percent in actual emissions throughput the plant.

The following Table 5.2-1 provides the summary of facility-wide emissions after modification, as included in the application:

Table 5.2-1 Facility-wide Emissions Summary

			Source														
			PAP Plants (201 & 205)			APAP Plant			Utility (Boilers and Generators)			Wastewater Plant			Total		
Pollutant			tpy			tpy			tpy			tpy			tpy		
PM			0.40			8.20			16.31			0.00			24.91		
PM10			0.40			0.00			16.31			0.00			16.71		
PM2.5			0.40			0.00			16.31			0.00			16.71		
SO2[1]			4.53			0.01			222.08			0.00			226.62		
NOx[1]			0.00			0.00			216.05			0.00			216.05		
VOC			5.73			7.86			9.40			5.42			28.42		
CO			0.00			0.00			83.52			0.00			83.52		
HAP/TAP	HAP	TAP	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy
Acetaldehyde	x	x							8.88E-04	2.13E-02	2.22E-04				8.88E-04		2.22E-04
Acrolein	x	x							1.29E-04	3.09E-03	3.26E-05				1.29E-04		3.26E-05
Aniline	x	x	1.527		2.870				1.67E+01	2.70E+01	9.70E-01				1.83E+01		3.84E+00
Antimony	x								8.12E-05	1.95E-03	3.56E-04				8.12E-05		3.56E-04
Arsenic	x	x							4.59E-04	1.10E-02	1.92E-03				4.59E-04		1.92E-03
Benzene	x	x	0.660		0.223				7.82E-02	2.75E-01	1.52E-02				7.38E-01		2.39E-01
Benzo(a)pyrene	x	x							2.25E-06	5.40E-05	4.15E-06				2.25E-06		4.15E-06
Beryllium	x	x							3.02E-04	7.25E-03	1.26E-03				3.02E-04		1.26E-03
Bromomethane	x	x							3.45E-03	8.27E-02	1.51E-02				3.45E-03		1.51E-02
1,3 Butadiene	x	x							3.98E-05	9.55E-04	9.95E-06				3.98E-05		9.95E-06
Cadmium	x	x							1.16E-03	2.79E-02	5.04E-03				1.16E-03		5.04E-03
Carbon Disulfide	x	x							1.87E-04	4.48E-03	8.18E-04				1.87E-04	4.48E-03	8.18E-04
Chlorine	x	x							1.64E-02	3.94E-01	7.18E-02				1.64E-02	3.94E-01	7.18E-02
Chloromethane	x								4.60E-02	1.10E+00	2.02E-01				4.60E-02		2.02E-01
Chromium	x								5.14E-02	1.23E+00	2.25E-01				5.14E-02		2.25E-01
Chromium (VI)	x	x							1.30E-03	3.12E-02	5.63E-03				1.30E-03	3.12E-02	5.63E-03
Cobalt	x								2.68E-05	6.44E-04	8.54E-05				2.68E-05		8.54E-05
Dichlorobenzene	x	x							2.67E-04	6.40E-03	1.17E-03				2.67E-04	6.40E-03	1.17E-03
Dioxins/Furans	x	x							2.18E-04	5.24E-03	7.54E-08				2.18E-04	5.24E-03	7.54E-08
Ethylbenzene	x								5.57E-04	1.34E-02	2.44E-03				5.57E-04		2.44E-03
Fluoride	x								2.54E-02	6.11E-01	1.11E-01				2.54E-02		1.11E-01
Formaldehyde	x	x							5.12E-02	1.23E+00	1.89E-01				5.12E-02		1.89E-01
Hexane	x	x							5.75E-01	1.38E+01	1.83E+00				5.75E-01	1.38E+01	1.83E+00
Hydrogen Chloride	x	x							5.35E-01	1.29E+01	2.35E+00				5.35E-01		2.35E+00
Iodomethane	x								5.24E-04	1.26E-02	2.30E-03				5.24E-04		2.30E-03
Lead	x								1.53E-03	3.67E-02	6.32E-03				1.53E-03		6.32E-03
Manganese	x	x							1.19E-03	2.86E-02	5.10E-03				1.19E-03	2.86E-02	5.10E-03
Mercury	x	x							1.90E-02	4.56E-01	8.32E-02				1.90E-02	4.56E-01	8.32E-02
Methyl Chloroform	x	x							1.61E-04	3.86E-03	7.05E-04				1.61E-04	3.86E-03	7.05E-04
Methylene Chloride	x	x							1.26E-03	3.04E-02	5.54E-03				1.26E-03		5.54E-03
Naphthalene	x								9.98E-04	2.40E-02	1.63E-03				9.98E-04		1.63E-03
Nickel	x	x							1.71E-02	4.10E-01	7.47E-02				1.71E-02	4.10E-01	7.47E-02
Nitrobenzene	x	x	1.459	25.343	2.642				3.56E-01	5.61E-01	1.80E-02				1.82E+00	2.59E+01	2.66E+00
Polychlorinated Biphenyls	x	x							7.71E-06	1.85E-04	3.38E-05				7.71E-06		3.38E-05
POMs	x								3.46E-03	8.30E-02	1.09E-02				3.46E-03		1.09E-02
Selenium	x								1.66E-03	3.98E-02	6.93E-03				1.66E-03		6.93E-03
Toluene	x	x							5.68E-02	1.36E+00	2.41E-01				5.68E-02	1.36E+00	2.41E-01
Vinyl Acetate	x								2.98E-03	7.16E-02	1.31E-02				2.98E-03		1.31E-02
Xylene	x	x							2.05E-03	4.93E-02	4.46E-03				2.05E-03	4.93E-02	4.46E-03
															Total HAPs (tpy) =		12.20
															Largest Individual HAP - Aniline (tpy) =		3.84
TAPs Only	HAP	TAP	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy	(lb/hr)	(lb/day)	tpy
Acetic Acid		x	0.000			2.19E+00						1.43E+00			3.61E+00		
Ammonia		x	5.680			8.49E-03			1.02E+00						6.71E+00		

1. SpecGx Mallinckrodt Pharmaceutical Company limits emissions of SO2 and NOx below 100 tons per year to avoid PSD.

5.3 Regulatory Applicability

The proposed changes are subject to the requirements in 02D .0524, .1100 and .1806, and 02Q .0317 and .0711.

15A NCAC 02D .0524 "New Source Performance Standards"

Subpart NNN "Standards of Performance for Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations"

Per §60.660(a) and (b), this Subpart applies to each distillation facility as below, for which construction, modification, or reconstruction commenced after December 30, 1983, that is part of a process unit that produces any of the chemicals listed in § 60.667 as a product, co-product, by-product, or intermediate:

- Each distillation unit not discharging its vent stream into a recovery system.
- Each combination of a distillation unit and the recovery system into which its vent stream is discharged.
- Each combination of two or more distillation units and the common recovery system into which their vent streams are discharged.

Paragraph (c) of §60.660 includes the following exemptions:

- Any distillation unit operating as part of a process unit which produces coal tar or beverage alcohols, or which uses, contains, and produces no VOC is not an affected facility.
- Any distillation unit that is subject to the provisions of Subpart DDD is not an affected facility.
- Any distillation unit that is designed and operated as a batch operation is not an affected facility.
- Each affected facility that has a total resource effectiveness (TRE) index value greater than 8.0 is exempt from all provisions of this Subpart, except for §§ 60.662; 60.664 (e), (f), and (g); and 60.665 (h) and (l).
- Each affected facility in a process unit with a total design capacity for all chemicals produced within that unit of less than one gigagram per year is exempt from all provisions of this Subpart, except for the recordkeeping and reporting requirements in paragraphs (j), (l)(6), and (n) of § 60.665.
- Each affected facility operated with a vent stream flow rate less than 0.008 scm/min is exempt from all provisions of this subpart, except for the test method and procedure and the recordkeeping and reporting requirements in § 60.664(g) and paragraphs (i), (l)(5), and (o) of § 60.665.

There are six distillation units in the PAP plant and one in the APAP plant. The facility produces aniline and acetic acid, as byproduct or co-product of the PAP manufacturing process, and both are listed chemicals in §60.667. Thus, five of the six distillation units in the PAP production processes are subject to the requirements of Subpart NNN. The lone distillation unit in the APAP production process is also subject to Subpart NNN requirements. A replacement aniline tar still was recently installed but not as part of the PAP expansion project. All other distillation equipment were neither modified nor replaced. A summary of the regulatory applicability and compliance status of these is presented in Table 5.3-1 below:

Table 5.3-1: Sources Subject to NSPS Subpart NNN

Description	Process/ Building	Applicability	Date Installed	Date Last Modified	Comments
Nitrobenzene Stripper Columns (C-209/C-101)	PAP/201 & PAP/205	Not Applicable	---	---	No SOCMI chemicals "produced" at this point in the PAP process.
201 Wastewater Stripper Column (C-105)	PAP/201	Subject to NNN, §60.660(c)(4) exemption	1976	March 1997	Continuous processing of aniline; partial exemption because TRE Index Value = 6,802 (i.e., >>8).
Organic Water Strip Column	PAP/201	Subject to NNN, §60.660(c)(4) exemption	1976	March 1997	Continuous processing of aniline; partial exemption because TRE Index Value = 2,032 (i.e., >>8); located on the Organic Water Strip Pot, T-219.
Aniline Stripper Column	PAP/201	Subject to NNN, §60.660(c)(4) exemption	1991	March 1997	Continuous processing of aniline; partial exemption because TRE Index Value = 23,132 (i.e., >>8).
Aniline/Tar Still Column (C-103)	PAP/205	Subject to NNN, §60.660(c)(4) exemption	October 2019	---	Originally a batch operation, converted to continuous processing (semi-batching) of aniline in March 1997 and unit replaced in October 2019; partial exemption because TRE Index Value = 1,932 (i.e., >>8).
Acetic Acid Evaporator	APAP/101	Subject to NNN, §60.660(c)(4) exemption	December 1998	---	Continuous processing of acetic acid; partial exemption because TRE Index Value = 68 (i.e., > 8).

Mallinckrodt complies with Subpart NNN for the distillation units in the PAP and APAP production process by maintaining the TRE Index values above 8 for these units without the use of controls, in accordance with §60.662(c). The TRE values for each unit are provided in Table 5.3-1 above. Calculations for the TRE Index values for each affected unit are kept onsite at the facility and are available for review upon request.

All distillation units subject to Subpart NNN are exempt from the majority of the recordkeeping and reporting requirements of the standard. Units falling under the §60.660(c)(4) partial exemption only have to report changes in the TRE index value in the semi-annual report. According to §60.664(f), the TRE index value must be recalculated whenever there is a process change such as changes in production capacity or in feedstock/catalyst type, or whenever there is replacement, removal, or addition of recovery equipment.

In summary, the existing permit includes all applicable requirements of Subpart NNN, and no revisions are required.

Subpart RRR "Standards of Performance for Volatile Organic Compound Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes"

Per §60.700(a) and (b), this Subpart applies to each reactor as below, for which construction, modification, or reconstruction commenced after June 29, 1990, that is part of a process unit that produces any of the chemicals listed in § 60.707 as a product, co-product, by-product, or intermediate:

- Each reactor process not discharging its vent stream into a recovery system.
- Each combination of a reactor process and the recovery system into which its vent stream is discharged.
- Each combination of two or more reactor processes and the common recovery system into which their vent streams are discharged.

Paragraph (c) of §60.700 includes the following exemptions:

- Any reactor process that is designed and operated as a batch operation is not an affected facility.
- Each affected facility that has a total resource effectiveness (TRE) index value greater than 8.0 is exempt from all provisions of this subpart except for §§ 60.702(c); 60.704 (d), (e), and (f); and 60.705 (g), (l)(1), (l)(6), and (t).
- Each affected facility in a process unit with a total design capacity for all chemicals produced within that unit of less than 1 gigagram per year (1,100 tons per year) is exempt from all provisions of this subpart except for the recordkeeping and reporting requirements in § 60.705 (i), (l)(5), and (n).
- Each affected facility operated with a vent stream flow rate less than 0.011 scm/min is exempt from all provisions of this subpart except for the test method and procedure and the recordkeeping and reporting requirements in §§ 60.704(g) and 70.705 (h), (l)(4), and (o).
- If the vent stream from an affected facility is routed to a distillation unit subject to subpart NNN and has no other releases to the air except for a pressure relief valve, the facility is exempt from all provisions of this subpart except for § 60.705(r).
- Any reactor process operating as part of a process unit which produces beverage alcohols, or which uses, contains, and produces no VOC is not an affected facility.
- Any reactor process that is subject to the provisions of Subpart DDD is not an affected facility.
- Each affected facility operated with a concentration of total organic compounds (TOC) (less methane and ethane) in the vent stream less than 300 ppmv as measured by Method 18 or a concentration of TOC in the vent stream less than 150 ppmv as measured by Method 25A is exempt from all provisions of this subpart except for the test method and procedure and the reporting and recordkeeping requirements in § 60.704(h) and paragraphs (j), (l)(8), and (p) of § 60.705.

There are several reactor units in the PAP plant. The facility produces aniline and acetic acid, as byproduct or co-product of the PAP manufacturing process, and both are listed chemicals in §60.707. The following reactors in the PAP plant are subject to Subpart RRR:

- T282 (Building 201)
- T284 (Building 201)
- T363 (Building 205)
- T365 (Building 205)

PAP Sulfate and aniline sulfate react with ammonia to precipitate PAP and aniline in these reactors. The process is continuous, with a simultaneous input of reactants and output of products. The T282 and T363 vessels also serve as crystallizer units intermittently and are rotated out of sequence with T284 and T365 to reduce solids buildup.

The RRR NSPS requires each subject source to determine the Total Resource Effectiveness (TRE) Index Value. The TRE value is determined based on prescriptive equations in §60.704(e) that includes vent stream flows, vent total organic carbon (TOC) emission rates, vent net heating values, and vent corrosion properties. The TRE values for a previously installed reactor (T284) and the three new reactors (T282, T363 & T365) were provided by Mallinckrodt process engineers and are as follows:

Table 5.3-2: Sources Subject to NSPS Subpart RRR

Reactor ID	Reactor Type	Date of Construction	Total Annual Aniline Design Capacity (tpy)	Vent Stream Flow Rate (scm/min)	TRE Index Value[1]
T282	Continuous	August 22, 2019	1,692	0.424	1,307
T284	Continuous	November 2, 2007	1,692	0.424	1,307
T363	Continuous	August 22, 2019	1,692	0.424	1,307
T365	Continuous	December 1, 2012	1,692	0.424	1,307

[1] The basis for the TRE values is provided in the application.

The TRE values for each reactor are greater than 8, making each unit subject to the limited recordkeeping, monitoring, and reporting requirements of NSPS RRR according to §60.700(c)(2) as below:

Standards

- Per §60.702(c), maintain a TRE index value greater than 1.0 without use of a VOC emission control device.

Test Methods and Procedures

- Per §60.704(d), the owner/operator shall use the test methods in Appendix A to Part 60, except as provided under § 60.8(b), for determining the net heating value of the gas combusted to determine compliance under § 60.702(b) and for determining the process vent stream TRE index value to determine compliance under §§ 60.700(c)(2) and 60.702(c).
- Per §60.704(e), for purposes of complying with §§ 60.700(c)(2) and 60.702(c), the owner or operator of a facility affected by this Subpart shall calculate the TRE index value of the vent stream using the equation for incineration in paragraph (e)(1) of this Section for halogenated vent streams. The owner or operator of an affected facility with a nonhalogenated vent stream shall determine the TRE index value by calculating values using both the incinerator equation in (e)(1) of this section and the flare equation in (e)(2) of this Section and selecting the lower of the two values.
- Per §60.704(f), each owner or operator of an affected facility seeking to comply with § 60.700(c)(2) or § 60.702(c) shall recalculate the TRE index value for that affected facility whenever process changes are made. Examples of process changes include changes in production capacity, feedstock type, or catalyst type, or whenever there is replacement, removal, or addition of recovery equipment. The TRE index value shall be recalculated based on test data, or on best engineering estimates of the effects of the change on the recovery system.

Reporting and Recordkeeping Requirements

- Per §60.705(g), each owner or operator of an affected facility subject to the provisions of this subpart and seeking to demonstrate compliance with § 60.702(c) shall keep up-to-date, readily accessible records of:
  - Any changes in production capacity, feedstock type, or catalyst type, or of any replacement, removal or addition of recovery equipment or reactors;
  - Any recalculation of the TRE index value performed pursuant to § 60.704(f); and
  - The results of any performance test performed pursuant to the methods and procedures required by § 60.704(d).

- Per §60.705(l), each owner or operator that seeks to comply with the requirements of this Subpart by complying with the requirements of § 60.700 (c)(2), (c)(3), or (c)(4) or § 60.702 shall submit to the Administrator semiannual reports

of the following recorded information. The initial report shall be submitted within 6 months after the initial start-up date. The report shall contain:

- Exceedances of monitored parameters recorded under § 60.705 (c), (f), and (g).
- Any recalculation of the TRE index value, as recorded under § 60.705(g).

- Per § 60.705(t), each owner or operator that seeks to demonstrate compliance with § 60.700(c)(2) must maintain a record of the initial test for determining the total resource effectiveness index and the results of the initial total resource effectiveness index calculation.

- The facility is subject to the initial notifications requirements for the affected reactors: (i) date construction (or reconstruction as defined under § 60.15) of an affected facility is commenced postmarked no later than 30 days after such date, and (ii) notification of the actual date of initial startup of an affected facility postmarked within 15 days after such date. Mallincrodt has indicated that it will submit a letter to the NCDAQ indicating startup.

Subpart VVa "Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry for Which Construction, Reconstruction, or Modification Commenced After November 7, 2006"

- Per §60.480a(a) and (b), the provisions of this Subpart apply to affected facilities in the synthetic organic chemicals manufacturing industry that commences construction, reconstruction, or modification after November 7, 2006. It applies to the group of all equipment (defined in § 60.481a) within a process unit is an affected facility.

> *Process unit* means the components assembled and connected by pipes or ducts to process raw materials and to produce, as intermediate or final products, one or more of the chemicals listed in § 60.489. A process unit can operate independently if supplied with sufficient feed or raw materials and sufficient storage facilities for the product. For the purpose of this subpart, process unit includes any feed, intermediate and final product storage vessels (except as specified in § 60.482-1a(g)), product transfer racks, and connected ducts and piping. A process unit includes all equipment as defined in this subpart.

SpecGx's Raleigh facility is currently subject to NSPS Subpart VV requirements for VOC emissions leaks. With the proposed modifications as discussed in this application, the facility will become subject to the Subpart VVa requirements; thus, the exiting VV Subpart will be removed and replaced with the applicable Subpart VVa requirements as below.

- If an affected facility produces heavy liquid chemicals only from heavy liquid feed or raw materials, then it is exempt from §§ 60.482-1a through 60.482-11a.

Record keeping Requirements

- Per §60.486a(2), an owner or operator of more than one affected facility subject to the provisions of this subpart may comply with the recordkeeping requirements for these facilities in one recordkeeping system if the system identifies each record by each facility.

- Per §60.486a(i), the following information shall be recorded in a log that is kept in a readily accessible location for use in determining exemptions as provided in § 60.480a(d):
  - An analysis demonstrating the design capacity of the affected facility,
  - A statement listing the feed or raw materials and products from the affected facilities and an analysis demonstrating whether these chemicals are heavy liquids or beverage alcohol, and
  - An analysis demonstrating that equipment is not in VOC service.

- Per §60.486a(j), information and data used to demonstrate that a piece of equipment is not in VOC service shall be recorded in a log that is kept in a readily accessible location.

Reporting Requirements

- Per 60.487a(a), each owner or operator subject to the provisions of this Subpart shall submit semiannual reports to the Administrator beginning 6 months after the initial startup date.

- Per 60.487a(b), the initial semiannual report to the Administrator shall include all applicable information. The only required information for each semi-annual reporting for SpecGx's Raleigh facility is with regard to the process unit identification. All other information required under this provision is not required to be reported as they apply to the standards for valves, pumps, compressors, and connectors in §60.482, which are not applicable to this facility.

- Per 60.487a(c), all semiannual reports to the Administrator shall include the following information, summarized from the information in § 60.486a: process unit identification and dates of process unit shutdowns which occurred within the semiannual reporting period. All other information required under this provision is not required to be reported as they apply to the standards for valves, pumps, compressors, and connectors in §60.482, which are not applicable to this facility.

15A NCAC 02D .0530 "Prevention of Significant Deterioration"

Refer to Section 6 for discussions.

15A NCAC 02D .1100 "Control of Toxic Air Pollutants"
15A NCAC 02Q .0700 "Toxic Air Pollutant Procedures"

Refer to Section 7 for details.

15A NCAC 02D .1806 "Control and Prohibition of Odorous Emissions"

The Permittee shall not operate the facility without implementing management practices or installing and operating odor control equipment sufficient to prevent odorous emissions from the facility from causing or contributing to objectionable odors beyond the facility's boundary. This requirement is state-enforceable only. The current permit adequately includes the requirement, and no change is warranted.

6. NSPS, NESHAP, PSD, Attainment Status, 112(r), and CAM

NSPS

The applicable NSPSs for the proposed modifications have been discussed in Section 5.3 above.

NESHAP

Based on Table 5.2-1, the facility is an area source for HAPs.

It needs to be emphasized that EPA added a new HAP (1-bromopropane (1-BP)) to the CAA §112(b) list and began regulating it effective February 4, 2022. As requested by NCDAQ, SpecGx responded via email of September 16, 2022 (included in Attachment 1) that it had reviewed Safety Data Sheets (SDS) of all raw materials used in the manufacturing of PAP and APAP, and determined that 1-BP was not present. The applicant had also certified that 1-BP is not manufactured (as a product or byproduct), processed, or otherwise used during the PAP and APAP manufacturing process.

In brief, the above cited emissions summary is accurate for all regulated air pollutants including the HAPs.

With regard to DAQ's question on applicability of National Emission Standards for Hazardous Air Pollutants for Chemical Manufacturing Area Sources" as codified in 40 CFR 63, Subpart VVVVVV, SpecGx replied that the facility was exempt from applicability to this NESHAP. Specifically, the facility is considered a chemical manufacturing process unit (CMPU); however, Mallinckrodt does not use as feedstocks, generate as a byproduct, or produce as

products any of the hazardous air pollutants listed in Table 1 of Part 63 Subpart VVVVVV in excess of concentrations listed under §63.11494(a)(3). Thus, it is exempt.

PSD

The facility is an existing minor source for PSD. It is a "chemical process plants" category source. The current permit includes the applicability limits (avoidance limits) for PSD for both NOx and SO_2 to keep the facility-wide emissions of each below 100 tons per year. If the physical change(s) by itself to such minor stationary source amounts to emissions of any regulated NSR pollutants at least 100 tons/yr (major source threshold), then that physical change becomes a major stationary source, and it requires a PSD permit. As shown in Table 6-1 below, the change in emissions due to the physical changes at the subject minor source do not amount to 100 tons/yr of increase for any regulated NSR pollutants. Thus, the proposed changes are not subject to PSD.

Table 6-1: PSD Applicability`

	Source				Projected Actual Emissions (PAE) Total	Baseline Actual (Average 2017-2018) Emissions (BAE)	Projected Emissions Increase (PEI) due to Project[1]	PSD Major Significance Threshold
	PAP Plants (201 & 205)	APAP Plant	Utility (Boilers and Generators)	Wastewater Plant				
Pollutant	**tpy**	**tpy**	**tpy**	**tpy**	**tpy**	**tpy**	**tpy**	**tpy**
PM	0.11	8.17	4.48	0.00	12.76	9.9	2.86	100
PM10	0.11	8.17	4.47	0.00	12.75	9.9	2.85	100
PM2.5	0.11	8.17	4.47	0.00	12.75	9.9	2.85	100
SO2	4.24	0.01	4.47	0.00	8.73	14	-5.27	100
NOx	0.00	0.00	51.77	0.00	51.77	43.55	8.22	100
VOC	5.58	4.06	2.89	4.70	17.23	18.7	-1.47	100
CO	0.00	0.00	38.40	0.00	38.40	29.5	8.90	100

[1] PEI = PAE – BAE

With regard to applicability, pre-project, baseline actual emissions (BAE) for the facility were estimated using the submitted emission inventories for 2017 and 2018. Post-project projected actual emissions (PAE) were determined for the modified units due to the project (PAP 201 & 205), in addition to anticipated emission increases from the debottlenecking of any up or downstream units or increased utilization of process or support units (APAP and utilities). The change in emissions (projected actual emissions - baseline actual emissions) were then compared to the major stationary source threshold (100 tons per year for "chemical process plants" category). DAQ has reviewed the emissions estimates and found them to be correctly prepared.

It needs to be clarified that the provision in 02D .0530(u) is not applicable here. Because the facility is an existing minor source (and not a major stationary source), and as discussed above, it will remain a minor source. DAQ's 02D .0530(u) provision applies to existing emissions units, undergoing modification(s), at an existing major stationary source (and not at a minor source), and if projected actual emissions are used for PSD applicability. The references to "significant emission rate" in this provision make it clear that the requirements in 02D .0530(u) are not applicable to the proposed modifications discussed in this application as this SpecGx facility is an existing minor source for PSD. Finally, as discussed earlier, physical changes to this minor source have been evaluated for applicability of major stationary source requirements.

Attainment Status

Wake County is currently in attainment or unclassifiable/attainment for all promulgated NAAQSs. This county has triggered increment tracking under PSD for SO_2. Emissions of this pollutant are expected to decrease by 1.20 lbs/hr due to the proposed changes discussed previously.

112(r)

This facility is subject to Section 112(r) of the Clean Air Act as per Section 2.3 of the current permit. The owner/operator is required to submit an update to the facility's current Risk Management Plan (RMP) no later than January 31, 2024.

CAM

Not applicable. The applicability to CAM is required to be evaluated during the processing of renewal and/or significant modification applications. This submitted application is not a renewal of the Title V permit. Further, the application, as stated above, is a significant modification per 02Q .0500, but it is to be processed under the construction and operation program in 02Q .0300 and not .0500. Thus, CAM applicability does not need to be addressed at this time.

7. Facility Wide Air Toxics

The facility is currently subject to the NC's air toxics program requirements in 02Q .0700 and 02D .1100. Specifically, the current permit includes the approved emissions limits for acetic acid, ammonia, aniline, arsenic, benzene, chlorine, hydrogen chloride, and nitrobenzene, demonstrating compliance with the applicable acceptable ambient levels (AALs).

Per 02Q .0706 "modifications", a permit is to emit toxic air pollutants is required if the modification results into a net increase in emissions of emissions or ambient concentration, as previously determined pursuant to 15A NCAC 02D .1106 and 15A NCAC 02Q .0709 of any toxic air pollutant that the facility was emitting before the modification, or if the facility wide emissions of any pollutant the facility was not emitting before the modification exceeds the applicable toxic pollutant emission rates (TPERs).

The PAP plant expansion project, as discussed earlier, resulted in an approximate output (product) increase of 15 percent. Uncontrolled TAP emissions from PAP-22 & PAP-23 (prior to PAP house scrubber or PAPSCRUB) and the hydrogenator flash arrestor tanks (PAP-1 & PAP-6) will increase due to the modifications. The applicant has stated that in the previous applications, the owner did not conservatively consider reductions in TAP emissions from the recovery devices (water packed scrubbers CD-PAP-1 and CD-PAP-6). Considering the reductions in emissions associated with these recovery devices for the changes included in this application and performing the netting of pre- and post-emissions result in increase in only ammonia emissions. Table 7-1 summarizes the pre- and post-project emissions changes for the NC-regulated air toxics pollutants due to the project.

Separately, Mallinckrodt has made some changes in modeling parameters and TAP (toxic air pollutant) emissions estimate for several sources in the facility since the last modeling demonstration. Thus, Mallinckrodt has included modeling demonstration for the facility-wide emissions of ammonia, aniline, benzene, and nitrobenzene to demonstrate continued compliance with NCDAQ offsite ambient limits (15A NCAC 2D .1104), regardless that net increase in emissions occurs only for ammonia. Tables 7-2 and 7-3 below provide the modeled emissions rates and predicted impacts, respectively.

Table 7-1: TAP Emissions Netting

Ammonia	Source	Pre-change	Post-change	Difference
		lbs/hr	lbs/hr	lbs/hr
	ES-Fugitives-PAP-21	4.85	4.85	0
	PAPSCRUB	0.2	0.83	0.63
	ES-Fugitives-APAP-20	8.49E-03	8.49E-03	0
	Total	**5.1**	**5.7**	**0.63**
Aniline	Source	Pre	Post	Difference
		lbs/hr	lbs/hr	lbs/hr
	PAP-1	0	2.43E-05	2.43E-05
	PAP-6	0	2.43E-05	2.43E-05
	ES-Fugitives-PAP-26	0.8738	0.3481	0

	PAPSCRUB	1	1	0
	ES-Fugitives-PAP-18	0.273	0.238	-0.035
	ES-Fugitives-PAP-19	0.137	0.119	-0.018
	ES-Fugitives-PAP-20	0.137	0.119	-0.018
	PAP-25T	0.0536	0.0536	0
	PAP-25R	0.0536	0.0536	0
	PAP-10	0.16	0.16	0
	CD-CCS	0.0283	0.0283	0
	BH-900	31.7	16.71	-14.99
	Total	**34.4**	18.8	-15.6
Benzene	Source	Pre	Post	Difference
		(lbs/yr)	(lbs/yr)	(lbs/yr)
	PAP-1	543	100.4	-442.6
	PAP-6	543	100.4	-442.6
	PAP-11	4.91	4.91	0
	PAP-12	2.85	2.85	0
	ES-Fugitives-PAP-18	0.08	0.021	-0.05915
	ES-Fugitives-PAP-19	0.04	0.010	-0.029575
	ES-Fugitives-PAP-20	0.04	0.010	-0.029575
	ES-Fugitive-PAP-26	0.008	0.0032	0
	PAPSCRUB	208.57	416.000	207.43
	BH-900	0	7.201	7.200761
	CD-CCS	2.016	2.016	0
	BH-7	1.23	1.230	0
	Total	**1,306**	**635**	**-671**

Nitrobenzene	Source	Pre-change	Post-change	Difference
		lbs/hr	lbs/hr	lbs/hr
	PAP-1	0.457	2.46E-02	-0.4324
	PAP-6	0.457	2.46E-02	-0.4324
	PAP-11	0.0276	0.0276	0
	PAP-12	0.162	0.162	0
	ES-Fugitives-PAP-18	0.273	0.238	-0.035
	ES-Fugitives-PAP-19	0.137	0.119	-0.018
	ES-Fugitives-PAP-20	0.137	0.119	-0.018
	CD-CCS	0.000135	0.000135	0
	PAPSCRUB	0.143	0.283	0.14
	ES-Fugitives-PAP-26	1.15	0.46	0
	BH-900	1.35	0.356	-0.994
	Total	**4.3**	**1.8**	**-2.5**
	Source	Pre	Post	Difference

		(lb/day)	(lb/day)	(lb/day)
	PAP-1	11	0.59	-10.41
	PAP-6	11	0.59	-10.41
	PAP-11	0.663	0.663	0
	PAP-12	3.89	3.89	0
	ES-Fugitives-PAP-18	6.55	5.712	-0.838
	ES-Fugitives-PAP-19	3.28	2.856	-0.424
	ES-Fugitives-PAP-20	3.28	2.856	-0.424
	CD-CCS	0.00324	0.00324	0
	PAPSCRUB	3.43	1.01	-2.42
	ES-Fugitives-PAP-26	3.43	1.38	0
	BH-900	32.4	0.56	-31.83947
	Total	**78.9**	**20.1**	**-58.8**

Table 7-2: Modeled Emissions Rates, Lbs/Hr

Model ID	Description	Type	Ammonia	Aniline	Benzene	Nitrobenzene
BH7	66 MMBtu/hr Boiler	point	--	--	1.405E-04	--
BH900	10,000 Gallon Aniline Tar Storage Tank	point	--	1.675E+01	8.254E-04	--
BH900A	Tar Tank - BH7 stack	point	--	--	--	3.571E-01
BH900B	Tar Tank - BH7 stack - 24-hr	point	--	--	--	2.302E-02
CCS	Cloud Chamber Scrubber on Boilers 2 & 7	point	--	2.833E-02	2.300E-04	1.350E-04
PAP1	Flash Arrestor Tank	point	--	2.430E-05	1.143E-02	2.460E-02
PAP10	Aniline Storage Tank	point	--	1.603E-01	--	--
PAP11	Nitrobenzene railcar / tanker truck unloading	point	--	--	5.600E-04	2.762E-02
PAP12	Nitrobenzene Storage Tank	point	--	--	3.254E-04	1.619E-01
PAP25R	Aniline Loading to Railcar	point	--	5.357E-02	--	--
PAP25T	Aniline Loading to Truck	point	--	5.357E-02	--	--
PAP6	Flash Arrestor Tank	point	--	2.429E-05	1.143E-02	2.460E-02
PAPSCR24	Scrubber for PAP Plant Equipment (24-hr Emission Rate)	point	--	--	--	4.206E-02
PAPSCRUB	Scrubber for PAP Plant Equipment	point	8.300E-01	1.000E+00	4.750E-02	2.833E-01
APAP20	Ammonia System Equipment Leaks - APAP Plant	volume	8.492E-03	--	--	--
PAP18A	Equipment Leaks - PAP Organic Recovery	volume	--	1.190E-01	1.190E-06	1.190E-01
PAP18B	Equipment Leaks - PAP Organic Recovery	volume	--	1.190E-01	1.190E-06	1.190E-01
PAP19	Equipment Leaks - Bldg 201	volume	--	1.190E-01	1.190E-06	1.190E-01
PAP20	Equipment Leaks - Bldg 205	volume	--	1.190E-01	1.190E-06	1.190E-01
PAP21A	Ammonia System Equipment Leaks - Bldg 201	volume	2.302E+00	--	--	--

Model ID	Description	Type	Ammonia	Aniline	Benzene	Nitrobenzene
PAP21B	Ammonia System Equipment Leaks - Bldg 205	volume	2.548E+00	--	--	--
PAP26A1	201 Cuno Filter Change	volume	--	8.730E-02	1.825E-07	1.190E-01
PAP26A2	201 Cuno Filter Change	volume	--	--	--	1.508E-02
PAP26B1	201 Pre NBS Cuno / Old Niagara Filter Change	volume	--	8.730E-02	1.825E-07	1.190E-01
PAP26B2	201 Pre NBS Cuno / Old Niagara Filter Change	volume	--	--	--	1.508E-02
PAP26C1	205 Old Cuno Filter Change	volume	--	8.730E-02	1.825E-07	1.190E-01
PAP26C2	205 Old Cuno Filter Change	volume	--	--	--	1.508E-02
PAP26D1	205 Old Cuno Filter Change	volume	--	8.730E-02	1.825E-07	1.190E-01
PAP26D2	205 Old Cuno Filter Change	volume	--	--	--	1.508E-02
PAP26E1	205 New Cuno for Mott Filter Change	volume	--	8.730E-02	1.825E-07	1.190E-01
PAP26E2	205 New Cuno for Mott Filter Change	volume	--	--	--	1.508E-02

Table 7-3: Predicted Impacts

Pollutant	Averaging Period	AAL ($\mu g/m^3$)	Maximum Modeled Impacts % of AAL
Ammonia	1-hour	2700	13%
Aniline	1-hour	1000	58%
Benzene	Annual	0.12	78%
Nitrobenzene	1-hour	500	94%
	24-hour	60	33%

The Air Quality Analysis Branch (AQAB) of the DAQ Permitting Section concluded on May 26, 2021 that "the air toxics modeling analysis of facility-wide TAP emissions adequately demonstrated compliance with Acceptable Ambient Levels (AALs) outlined in 15A NCAC 02D.1104, on a source-by-source basis."

Moreover, based on DAQ request, the applicant conducted additional modeling analysis for emissions of ammonia for facility-wide sources. Because the above modeling accounted for ammonia emissions of only boiler BH-7, but not the other boilers BH-2, BH-5, BH-6, and BH-Temp, and since the facility-wide emissions of ammonia exceeded the applicable TPER. For other pollutants, additional modeling was not warranted (aniline, benzene, and nitrobenzene). The predicted impact of ammonia emissions is estimated to be 11.1 percent of AAL, based on the revised modeling (AQAB approval date May 4, 2023). The following Table 7-4 provides approved limits for ammonia for various sources:

Table 4: Approved Ammonia Emissions Rates

Source ID	Ammonia lbs/hr
PAPSCRUB	0.833
BH7	0.207
BH5	0.302
BH6	0.107
BH2	0.0960
BHTEMP	0.311
PAP21A	2.30
PAP21B	2.55
APAP20	0.00849

In summary, the DAQ will include in the revised permit, approved emissions rates for ammonia, aniline, benzene, and nitrobenzene for all sources listed in Tables 7-2 and 7-4 above, except the NESHAP-subject boilers BH-2, BH-5, and

BH-7, consistent with 02Q .0702(a)(27)(B). Finally, since the modeling demonstration indicates compliance with the applicable AALs, unacceptable risk to human health is not expected, even if the approved emissions limits for these boilers are not included in the permit.

8. Other Requested Changes

The applicant has requested to revise the feed rate limits and operating parameter limits for Boilers 2 and 7, included in Section 2.1 D.5.j and m, respectively. The owner/operator conducted compliance stack tests on December 10-11, 2019, as required, for demonstrating compliance with various requirements under NESHAP Subpart EEE "National Emission Standards for Hazardous Air Pollutants from Hazardous Waste Combustors" in 40 CFR 63, Subpart EEE. The DAQ's Stationary Source Compliance Branch (SSCB) approved the compliance tests on April 6, 2022 (Boiler 7) and June 24, 2022 (Boiler 2). The following permit language includes both the revised values (in **bold**) for the feed rate limits and operating parameter limits along with the respective current values (in ~~strike-out~~). In summary, the DAQ will implement these changes in the revised permit.

Section 2.1 D.5.j

Feed Rate Limits & the Feed Stream Analysis Plan [40 CFR 63.1209]

j. The Permittee shall comply with the following feed rate limits:
   i. DRE and Dioxin and Furan:
      (A) The maximum total hazardous waste feed rate to this source **(ID No. BH-2)** is ~~1,071~~ **1,077** lb/hr on a rolling 1-hour average basis.
      (B) The maximum total hazardous waste feed rate to this source **(ID No. BH-7)** is 1,544.6 lb/hr on a rolling 1-hour average basis.
      [40 CFR 63.1209(j)(3), (k)(4)]
   ii. Mercury:
      (A) The maximum mercury feed rate is ~~1.39E-4~~ **5.55E-4** pounds per million Btu for this source **(ID No. BH-2)**. The averaging period for the mercury feed rate shall not exceed one year.
      (B) The maximum mercury feed rate is ~~3.73E-6~~ **3.97E-6** pounds per million Btu for this source **(ID No. BH-7)**. The averaging period for the mercury feed rate shall not exceed one year.
      [40 CFR 63.1209(l)(1)(ii)]
   iii. Ash:
      (A) The maximum ash feed rate limit is ~~7.03~~ **5.02** lb/hr for this source **(ID No BH-2).** The ash feed rate shall not exceed this limit on a rolling 12-hour average basis.
      (B) The maximum ash feed rate limit for this source **(ID No. BH-7)** shall be the feed rate the Permittee uses to demonstrate compliance with the particulate limit in 40 CFR 266.105.
      [40 CFR 63.1209(m)(3)]
   iv. Semivolatile Metals (Cadmium and Lead):
      (A) The maximum semivolatile metal feed rate is ~~4.87E-03~~ **1.25E-02** pounds per million Btu for this source **(ID No. BH-2)**. The averaging period for the semivolatile metal feed rate shall not exceed one year.
      (B) The maximum semivolatile metal feed rate limit for this source **(ID No. BH-7)** shall be the feed rate the Permittee uses to demonstrate compliance with the cadmium and lead limits in 40 CFR 266.106.
      [40 CFR 63.1209(n)(2)(v)(A)]
   v. Chromium:
      (A) The maximum chromium feed rate limit is ~~1.83E-02~~ **9.15E-02** pounds per million Btu for this source **(ID No BH-2)**. The chromium feed rate to shall not exceed this limit on a rolling 12-hour average basis.
      (B) The maximum chromium feed rate limit for this source **(ID No. BH-7)** shall be the feed rate the Permittee uses to demonstrate compliance with the chromium limit in 40 CFR 266.106.
      [40 CFR 63.1209(n)(2)(v)(B)]

vi. Hydrogen chloride and chlorine:
(A) The maximum total chlorine and chloride feed rate limit for this source **(ID No. BH-2)** is ~~7.03E-01~~ **3.68E-01** pounds per million Btu of chlorine (organic and inorganic). The total chlorine and chloride feed rate shall not exceed this limit on a rolling 12-hour average basis.
(B) The maximum total chlorine and chloride feed rate limit for this source **(ID No. BH-7)** is ~~8.13E-01~~ **2.62E-01** pounds per million Btu of chlorine (organic and inorganic). The total chlorine and chloride feed rate shall not exceed this limit on a rolling 12-hour average basis.
[40 CFR 63.1209(o)(1)(ii)]

vii. To remain in compliance with 15A NCAC 02D .1111 and 40 CFR Part 63 Subpart EEE for particulate matter, cadmium and lead, and chromium, the Permittee shall ensure the maximum feed rates of hazardous waste and ash to this source **(ID No. BH-7)** shall not exceed the rates the Permittee uses to demonstrate compliance with 40 CFR 266.105 and .106. These parameters shall be monitored and measured in accordance with the Feed Stream Analysis Plan specified in 2.1 D.5.k above.

The Permittee shall be deemed in non-compliance with 15A NCAC 02D. 1111 if the feed rate limits in Section 2.1.D.5.j.i through vii above are exceeded.

Section 2.1 D.5.m

Operating Parameter Limits [40 CFR 63.1209]

m. The Permittee shall comply with the following parameter limits:
i. DRE and Dioxin and Furan:
(A) The combustion chamber temperature for this source **(ID No. BH-2)** shall not fall below ~~1,829~~ **1,884** °F on a rolling 1-hour average basis.
(B) The combustion chamber temperature for this source **(ID No. BH-7)** shall not fall below 1,261.7 °F on a rolling 1-hour average basis.
[40 CFR 63.1209(j)(1), (k)(2)]

ii. All:
(A) The stack ID fan speed for this source **(ID No. BH-2)** shall not exceed ~~802.2~~ **586.6** RPM on a rolling 1-hour average basis.
(B) The stack ID fan speed for this source **(ID No. BH-7)** shall not exceed ~~1506.2~~ **1606.7** RPM on a rolling 1-hour average basis.
[40 CFR 63.1209(j)(2) , (k)(3), (l)(2), (m)(2), (n)(5), (o)(2), (o)(3)(v)]

iii. DRE:
(A) The minimum atomizing steam pressure switch shall not fall below 80 psi for this source **(ID No. BH-2)**, as provided by the manufacturer's specification, on a 1-minute average basis.
(B) The minimum atomizing steam pressure switches shall not fall below 45 psi for this source **(ID No. BH-7)**, as provided by the manufacturer's specification, on a 1-minute average basis.
[40 CFR 63.1209(j)(4)]

iv. Mercury, Hydrogen Chloride, and Chlorine: The feed pressure of the scrubber water to the preconditioning chamber shall not fall below 10.0 psig on a rolling 1-hour average basis. *[40 CFR 63.1209(m)(1)(iv)]*

v. Mercury, Hydrogen Chloride, and Chlorine:
(A) For this source **(ID No. BH-2)** the pH of the scrubber water exiting the preconditioning chamber shall not fall below ~~6.35~~ **6.29** on a rolling 1-hour average basis;
(B) For this source **(ID No. BH-2) t**he pH of the scrubber water exiting the Cloud Generating Vessel sump shall not fall below ~~6.33~~ **6.28** on a rolling 1-hour average basis;
(C) For this source **(ID No. BH-7)** the pH of the scrubber water exiting the preconditioning chamber shall not fall below ~~6.81~~ **6.41** on a rolling 1-hour average basis; and,
(D) For this source **(ID No. BH-7) t**he pH of the scrubber water exiting the Cloud Generating Vessel sump shall not fall below ~~6.40~~ **6.43** on a rolling 1-hour average basis.
[40 CFR 63.1209(l)(1)(ii)(D)(3) and 40 CFR 63.1209(o)(3)(iv)]

vi. Mercury, Hydrogen Chloride, and Chlorine:
(A) For this source **(ID No. BH-2)** the flow rate of the scrubber water to the preconditioning chamber shall not fall below ~~956.0~~ **954.4** gallons per minute (gpm) on a rolling 1-hour average basis;
(B) For this source **(ID No. BH-2)** the flow rate of the scrubber water to the No. 1 Cloud Generating Vessel shall not fall below ~~271.3~~ **317.3** gpm on a rolling 1-hour average basis;

(C) For this source **(ID No. BH-2)** the flow rate of the scrubber water to the No. 2 Cloud Generating Vessel shall not fall below ~~246.6~~ **305.8** gpm on a rolling 1-hour average basis;
(D) For this source **(ID No. BH-7)** the flow rate of the scrubber water to the preconditioning chamber shall not fall below ~~999.4~~ **959.6** gpm on a rolling 1-hour average basis;
(E) For this source **(ID No. BH-7)** the flow rate of the scrubber water to the No. 1 Cloud Generating Vessel shall not fall below ~~282.9~~ 315.2 gpm on a rolling 1-hour average basis; and
(F) For this source **(ID No. BH-7)** the flow rate of the scrubber water to the No. 2 Cloud Generating Vessel shall not fall below ~~255.5~~ **304.0** gpm on a rolling 1-hour average basis.

[40 CFR 63.1209(l)(2), (o)(3)(v)]

vii. Particulate Matter and Semi/Low-Volatile Metals:
(A) For this source **(ID No. BH-2)** the blowdown rates, measured by the flow meter located immediately downstream of the preconditioning chamber sump, shall not fall below ~~19.19~~ **19.45** gpm on a rolling 1-hour average basis.
(B) For this source (**ID No. BH-7)** the blow down rates, measured by the flow meter located immediately downstream of the preconditioning chamber sump, shall not fall below 25.79 gpm on a rolling 1-hour average basis.

[40 CFR 63.1209(m)(1)(i)(B)(1), 40 CFR 63.1209 (n)(3)]

viii. Particulate Matter and Semi/Low-Volatile Metals:
(A) No. 1 Cloud Generating Vessel:
(1) For this source **(ID No. BH-2)** the voltage on charging head #1A shall not fall below ~~11.006~~ **10.998** kV on a rolling 1-hour average basis; and,
(2) For this source **(ID No. BH-2)** the voltage on charging head #1B shall not fall below ~~10.988~~ **10.989** kV on a rolling 1-hour average basis.
(3) For this source (**ID No. BH-7)** the voltage on charging head #1A shall not fall below 11.054 kV on an hourly rolling average basis; and,
(4) For this source (**ID No. BH-7)** the voltage on charging head #1B shall not fall below 10.748 kV on an hourly rolling average basis.
(B) No. 2 Cloud Generating Vessel:
(1) For this source **(ID No. BH-2)** the voltage on charging head #2A shall not fall below ~~10.967~~ 11.007 kV on a rolling 1-hour average basis;
(2) For this source **(ID No. BH-2)** the voltage on charging head #2B shall not fall below ~~11.004~~ **11.007** kV on a rolling 1-hour average basis;
(3) For this source (**ID No. BH-7)** the voltage on charging head #2A shall not fall below 11.014 kV on an hourly rolling average basis; and,
(4) For this source (**ID No. BH-7)** the voltage on charging head #2B shall not fall below 11.506 kV on an hourly rolling average basis.

[40 CFR 63.1209(m)(1)(iv), (n)(3)]

ix. Particulate Matter and Semi/Low-Volatile Metals:
(A) Preconditioning Chamber: The minimum scrubber water liquid level in the preconditioning chamber shall not fall below approximately 32 inches, as provided by the manufacturer's specification, on an instantaneous (one-minute average) basis.
(B) No. 2 Cloud Generating Vessel: The minimum scrubber water liquid level in the No. 2 Cloud Generating Vessel sump shall not fall below approximately 32 inches, as provided by the manufacturer's specification, on an instantaneous (one-minute average) basis.

[40 CFR §63.1209(m)(1)(i)(B)(1)(ii), (n)(3)]

x. Except during performance tests and/or pre-testing, as provided for in 40 CFR 63.1207(h), the Permittee shall be deemed in noncompliance with 02D .1111 if not operating within the limits as specified in Section 2.1 D.5.m.i through ix above.

9. Facility Emissions Review

Page 1 of this application review above includes the actual emissions for 2016 through 2020.

10. Public Notice/EPA and Affected State(s) Review

Application processing pursuant to 02Q .0300 generally does not require public participation, and EPA and affected states review.

11. Stipulation Review

The following changes were made to the SpecGx LLC - Mallinckrodt Pharmaceuticals' Air Permit No. 01479T61:

Page	Section	Description of Changes
Cover letter and first page of permit		Revised the permit numbers and application number. Removed the previous minor modification approval for the temporary boiler from the cover letter.
2	Table of Contents	Renumbered the section for IAs from Section 2.3 to Section 3.
4	Section 2.1 Table	Specified the applicability of NSPS RRR to Buildings 201 and 205 equipment. Replaced the applicability of NSPS Subpart VV with Subpart VVa for ES-Fugitives. Removed the footnote for the previous minor modification approval for the temporary boiler. Included a footnote for this 1st step of two-step 501(b)(2) significant modification approval for the PAP expansion project equipment (Application 9200349.20B).
7	Section 2.1 A Table	Included the applicable requirement of NSPS Subpart RRR for the reactor processes. Replaced the existing requirement under NSPS Subpart VV with NSPS Subpart VVa for the distillation units. Included the applicable requirement in 02Q .0504.
7-8	Section 2.1 A.1	Replaced the existing requirement under NSPS Subpart VV with NSPS Subpart VVa for the distillation units.
9-10	Section 2.1 A.3	Included the new applicable requirement under NSPS Subpart RRR.
13	Section 2.1 C Table	Included the applicable requirement in 02Q .0504.
19-22	Section 2.1 D.5.j and m	Revised the feed rate limits and operating parameter limits for both boilers BH-2 and BH-7 as per the approved stack tests results.
31-33	Section 2.2 A.2.a.	Revised the emissions limits for ammonia, aniline, benzene, and nitrobenzene for various sources. Revised the approval dates in paragraph i. for new modeling for ammonia, aniline, benzene, and nitrobenzene due to the proposed modifications.
33	Section 2.2 A.2.b	Revised the operation timings for K083 liquid waste storage tank from 7 AM - 7 PM to 8 AM - 7 PM, based on the approved modeling.
35	Section 2.2 B.1	Included the applicable requirement in 02Q .0504.
36	Section 2.3	Renumbered the Section.
37	Section 3	Renumbered the Section for the approved IAs.
38-46	Section 4	Renumbered the Section.

12. Conclusions, Comments, and Recommendations

- The application does involve existing emissions sources to be modified along with the existing control devices (condensers and a packed tower scrubber). Thus, consistent with 02Q .0112 "Applications Requiring Professional Engineer Seal" the applicant has provided a professional engineer (PE) seal for the emissions calculations and control device forms (C Forms). Mr. Wesley Z. Brummer (NC PE No. 036862), consultant for

the applicant, sealed the above stated technical portions of the application. Mr. Brummer's PE license status is "current" per North Carolina Board of Examiners for Engineers and Surveyors' website.

- Pursuant to 02Q .0304(b)(1), the applicant has included a copy of the zoning consistency determination request, sent to the City of Raleigh via email and as well as Fedex on December 18, 2020. The city acknowledged the receipt of the zoning request via email on the same day.

- The draft permit was emailed to the Permittee for review on May 25, 2023. The Permittee was granted additional time for reviewing it until June 16, 2023. Tim Roberts from SpecGx emailed on June 13, 2023 various comments on the draft permit. All comments have been copied in verbatim and the DAQ responses have been provided below:

  Comment 1:

  "Please process the application under the two-step significant modification procedures pursuant to 15A NCAC 02Q .0501(b)(2). SpecGx LLC – Mallinckrodt Pharmaceuticals (Mallinckrodt) originally submitted the application as a one-step application and included all the appropriate Title V NCDAQ-E Forms. Much of the equipment has been installed and is now operating, some prior to the submission of the application. Mallinckrodt requests that the agency process the second part of the application using the information already provided in the original application, if possible. The fee for both parts was submitted in December 2020. "

  Response:

  The facility can use some of the same materials (forms, discussions on emissions, regulatory texts, etc.), used for preparing the Part 1 application, when it submits the Part 2 application for the same modification. Applicant should indicate in the Part 2 application that the processing fee for Part 2 application has been submitted previously when Part 1 application was submitted.

  Comment 2:

  Air Permit Condition 2.1.A.3.c should read as follows:

  Testing [15A NCAC 02Q .0308(a) and 40 CFR 60.704(d)]

  c. If emission testing is required, the testing shall be performed in accordance with General Condition JJ and 40 CFR 60.704. If the results of this test do not meet the standards set in Section 2.1 A.3.b, the Permittee shall be deemed in noncompliance with 15A NCAC 02D .0524.

  Response:

  DAQ has cited the stack testing requirements in General Condition JJ for this permit condition. This General Condition then points to the testing requirements in NSPS (02D .0524) and requires compliance with NSPS procedures for stack testing for any subject source. Thus, there is no need to refer to 40 CFR 60.704 (NSPS) for testing requirements. Further, a noncompliance statement for this permit term will be inserted when processing the Part 2 application for the same change, as Part 1 application processing is undertaken through construction and operation permits program in 02Q .0300 (and not through 02Q .0500). No change to the permit term will be made.

  Comment 3:

  The following Air Permit Conditions 2.1 D.5.j (Subpart EEE) conditions need to be modified:

vi. Hydrogen chloride and chlorine:

(A) The maximum total chlorine and chloride feed rate limit for this source **(ID No. BH-2)** is ~~7.03E-01~~ **3.68E-01** pounds per million Btu of chlorine (organic and inorganic). The total chlorine and chloride feed rate shall not exceed this limit on a rolling 12-hour average basis.

(B) The maximum total chlorine and chloride feed rate limit for this source **(ID No. BH-7)** is ~~8.13E-01~~ **2.62E-01** pounds per million Btu of chlorine (organic and inorganic). The total chlorine and chloride feed rate shall not exceed this limit on a rolling 12-hour average basis.

[40 CFR 63.1209(o)(1)(ii)]

Response:

DAQ will correct both the maximum total chlorine and chloride feed rate limits for source (ID No. BH-2), and maximum total chlorine and chloride feed rate limits for source (ID No. BH-7). The correct limits are 3.68E-01 pounds per million Btu of chlorine (organic and inorganic) and 2.62E-01 pounds per million Btu of chlorine (organic and inorganic), respectively.

Comment 4:

The following Air Permit Conditions 2.1 D.5.m (Subpart EEE) conditions need to be modified:

vii. Particulate Matter and Semi/Low-Volatile Metals:

(A) For this source **(ID No. BH-2)** the blowdown rates, measured by the flow meter located immediately downstream of the preconditioning chamber sump, shall not fall below ~~19.19~~ **19.45** gpm on a rolling 1-hour average basis.

Response:

DAQ will correct the blowdown rates value for source (ID No. BH-2) to 19.45 gpm.

Comment 5:

Pursuant to application 9200349.20B, these emission sources **(ID Nos. PAP-1, PAP-6, PAP-22, PAP-23, BH-900, and ES-~~Fugtives~~ Fugitives)** are listed as a 15A NCAC 02Q .0501(b)(2) modification. The Permittee shall file a Title V Air Quality Permit Application on or before 12 months after commencing operation of any of these ~~new~~ new or modified emission source(s) and/or control device(s) in accordance with General Condition NN. The permit shield described in General Condition R does not apply and annual compliance certification as described in General Condition P is not required.

Response:

DAQ will correct the typographical error in "fugitives" in Section 1 Table footnote and revise the footnote to state that Part 2 application is due within 12 months of issuance of the air permit 01479T62, as almost all of the equipment approved through this permit revision has commenced operation. DAQ will also make this change regarding the due date of submittal of Part 2 application in Section 2.2 B.1 of the permit.

Comment 6:

All process units producing SOCMI chemicals in the PAP manufacturing process (PAP-22, PAP-23, & ES-Fugitives) are considered "heavy liquid service" throughout. The PAP process is exempt from the 40 CFR Part 61 Subpart VVa Standards (40 CFR Part 60.482-1a through 60.482-11a) as specified by 40 CFR Part 60.480a(d)(3).

Because the General Standards are not applicable, the monitoring and recordkeeping of leaks from process equipment is not required. Many of these general standards have conditions which limit the duration of process unit operation before repairs are required to be completed. Any process unit shutdown due to repair of these leaks must be documented to show compliance with the general standards. Since the general standards are not applicable, the reporting of process unit shutdowns does not provide evidence of compliance with the standard,

nor does it provide any insight into the performance of the process unit. Mallinckrodt requests the air permit conditions 2.1.A.1.c be replaced by the following language:

Reporting [15A NCAC 02Q .0308(a) and 40 CFR 60.487a(a) through (c)]

c. The Permittee shall submit a summary report of the recordkeeping requirements given in Section 2.1 A.1.b above postmarked on or before January 30 of each calendar year for the preceding six-month period between July and December and July 30 of each calendar year for the preceding six-month period between January and June. All instances of deviations from the requirements of this permit must be clearly identified.

Response:

DAQ agrees with the applicant that the PAP sources subject to NSPS VVa are not "process units"; thus, the reporting requirements under this NSPS for process units do not apply to the subject sources PAP-18, PAP-19, PAP-20, all part of ES-Fugitives). Thus, as proposed by the applicant, DAQ will revise the permit condition and include semi-annual reporting for record keeping activities. Moreover, as stated previously in response to comment 2 above, a noncompliance statement for this permit term will be inserted when processing the Part 2 application.

Comment 7:

Air Permit Condition 2.1 A.1.b should be amended as follows:

Recordkeeping [15A NCAC 02~~D~~Q .0308(a) and 40 CFR 60.486a(i)(2)]

b. For facilities that are complying with the limited requirements for heavy liquid service, the Permittee shall retain a statement listing the feed or raw materials and products from the affected facilities and an analysis demonstrating whether these chemicals are heavy liquids.

Response:

This regulation citation will be corrected from "02D" to "02Q".

Comment 8:

Summary of Changes to Permit Table. Revise the following row:

Page	Section	Description of Changes
33	Section 2.2 A.2.b	Revised the operation timings for K083 liquid waste storage tank from ~~8 am~~ 7 AM – ~~8 pm~~ 7 PM to 8 AM – 7 PM, based on the approved modeling.

Response:

This change will be made.

Comment 9:

Page 31 through 33 – Air Toxic Limit Updates

Correct the emissions limits for aniline for:

(i) PAP Building 201 Fugitives (ID No. ES-Fugitives-PAP-19), from 0.137 lbs/hr to 0.119 lbs/hr, and
(ii) PAP Building 205 Fugitives (ID No. ES-Fugitives-PAP-20), from 0.137 lbs/hr 0.119 lbs/hr.

Correct the emissions limits for nitrobenzene for:

(i) Hydrogenerators (ID No. PAP-6), from 0.457 lbs/hr to 0.0246 lbs/hr, and 11.0 lbs/day to 0.59 lbs/day, and
(ii) PAP Filter Changes (ID No. ES-Fugitives-PAP-26), from 0.67 lbs/hr to 0.6 lbs/hr, and 16.09 lbs/day to 1.8 lbs/day.

Response:

These corrections to the emissions limits for both aniline and nitrobenzene will be made in Section 2.2 A.2.a. Table.

- The draft permit was emailed to the Raleigh Regional Office (RRO) on May 25, 2023. Dena Pittman emailed on June 2nd stating that RRO did not have any comment on the draft permit.
- The review engineer recommends issuing the revised permit.

Attachment 1
1-Bromopropane Air Emissions Determination
(SpecGx Letter, September 16, 2022)

Mallinckrodt Pharmaceuticals

September 16, 2022

Ms. Taylor Hartsfield, Regional Supervisor
NCDEQ – Division of Air Quality, Raleigh Regional Office
3800 Barrett Drive
Raleigh, NC 27609

RE: Mallinckrodt-Raleigh Pharmaceutical Plant (SpecGx LLC)
Raleigh, Wake County, North Carolina
Air Permit No. 01479T61, Facility ID: 9200349
1-bromopropane Air Emissions Determination

Dear Ms. Hartsfield:

1-bromopropane was recently added to the USEPA's list of hazardous air pollutants (HAPs). SpecGx LLC – Mallinckrodt Pharmaceuticals (Mallinckrodt) has reviewed Safety Data Sheets (SDS) for all raw materials used in the manufacture of para-amino phenol (PAP) and acetic para-amino phenol (APAP) and determined 1-bromopropane is not present. Mallinckrodt has also determined that 1-bromopropance is not manufactured (as a product or byproduct), processed, or otherwise used during the PAP and APAP manufacturing process.

Should you have any questions please contact Tim Roberts at (919) 878-2822.

I certify under penalty of law that this document was prepared under my direction and supervision in accordance with a system designed to ensure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering this information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Sincerely,
SpecGx LLC

David Phillips
Site Director

ec: Rahul Thaker (NCDAQ – Central Office)
Wes Brummer (Leaf Environmental & Engineering, P.C.)

Submitted Via Federal Express – Tracking # 777938693572

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