PERMIT BOOK

STATE OF MISSOURI

DEPARTMENT OF NATURAL RESOURCES

MISSOURI AIR CONSERVATION COMMISSION

PERMIT TO CONSTRUCT

Under the authority of RSMo 643 and the Federal Clean Air Act the applicant is authorized to construct the air contaminant source(s) described below, in accordance with the laws, rules and conditions as set forth herein.

Permit Number: 072014-004

Project Number: 2014-03-034
Installation Number: 510-0017

Parent Company: Mallinckrodt LLC

Parent Company Address: 675 McDonnell Boulevard, St. Louis, MO 63042

Installation Name: Mallinckrodt LLC

Installation Address: 3600 North Second Street, St. Louis, MO 63147

Location Information: City of St. Louis

Application for Authority to Construct was made for:
Installation of a Pharmaceutical X PMPU. This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060 *Construction Permits Required.*

☐ Standard Conditions (on reverse) are applicable to this permit.

☑ Standard Conditions (on reverse) and Special Conditions are applicable to this permit.

JUL 15 2014
EFFECTIVE DATE

Kyra L. Moore
DIRECTOR OR DESIGNEE
DEPARTMENT OF NATURAL RESOURCES

STANDARD CONDITIONS:

Permission to construct may be revoked if you fail to begin construction or modification within two years from the effective date of this permit. Permittee should notify the Air Pollution Control Program if construction or modification is not started within two years after the effective date of this permit, or if construction or modification is suspended for one year or more.

You will be in violation of 10 CSR 10-6.060 if you fail to adhere to the specifications and conditions listed in your application, this permit and the project review. In the event that there is a discrepancy between the permit application and this permit, the conditions of this permit shall take precedence. Specifically, all air contaminant control devices shall be operated and maintained as specified in the application, associated plans and specifications.

You must notify the Department's Air Pollution Control Program of the anticipated date of start-up of these air contaminant sources. The information must be made available within 30 days of actual startup. Also, you must notify the Department of Natural Resources Regional office responsible for the area within which you are located within 15 days after the actual startup of these air contaminant sources.

A copy of this permit and permit review shall be kept at the installation address and shall be made available to Department of Natural Resources' personnel upon request.

You may appeal this permit or any of the listed special conditions to the Administrative Hearing Commission (AHC), P.O. Box 1557, Jefferson City, MO 65102, as provided in RSMo 643.075.6 and 621.250.3. If you choose to appeal, you must file a petition with the AHC within 30 days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed. If it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the AHC.

If you choose not to appeal, this certificate, the project review and your application and associated correspondence constitutes your permit to construct. The permit allows you to construct and operate your air contaminant sources(s), but in no way relieves you of your obligation to comply with all applicable provisions of the Missouri Air Conservation Law, regulations of the Missouri Department of Natural Resources and other applicable federal, state and local laws and ordinances.

The Air Pollution Control Program invites your questions regarding this air pollution permit. Please contact the Construction Permit Unit at (573) 751-4817. If you prefer to write, please address your correspondence to the Missouri Department of Natural Resources, Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102-0176, attention: Construction Permit Unit.

SPECIAL CONDITIONS:

The permittee is authorized to construct and operate subject to the following special conditions:

The special conditions listed in this permit were included based on the authority granted the Missouri Air Pollution Control Program by the Missouri Air Conservation Law (specifically 643.075) and by the Missouri Rules listed in Title 10, Division 10 of the Code of State Regulations (specifically 10 CSR 10-6.060). For specific details regarding conditions, see 10 CSR 10-6.060(12)(A)10. "Conditions required by permitting authority."

Mallinckrodt LLC
City of St. Louis

1. Operational Limitation
   A. Mallinckrodt LLC shall exclusively use the following equipment to produce Pharmaceutical X:
      - EP-1820 BF-030 SS 2.25 m^2 Belt Filter
      - EP-1821 VP-837 (3) 50 gallon Filtrate Receivers and Vacuum Pump
      - EP-1822 T-032 750 gallon Aqueous Slurry Tank

REVIEW OF APPLICATION FOR AUTHORITY TO CONSTRUCT AND OPERATE
SECTION (5) REVIEW
Project Number: 2014-03-034
Installation ID Number: 510-0017
Permit Number:

Mallinckrodt LLC
3600 North Second Street
St. Louis, MO 63147

Complete: April 16, 2014

Parent Company:
Mallinckrodt LLC
675 McDonnell Boulevard
St. Louis, MO 63042

City of St. Louis

REVIEW SUMMARY

- Mallinckrodt LLC has applied for the authority to install EP-1820 BF-030 SS 2.25 m^2 Belt Filter, EP-1821 VP-837 (3) 50 gallon Filtrate Receivers and Vacuum Pump, and EP-1822 T-032 750 gallon Aqueous Slurry Tank in Building 260 to increase the production rate of their existing Pharmaceutical X PMPU.

- HAP emissions are expected from the proposed equipment. The material entering the Pharmaceutical X PMPU contains 33 weight percent of the solvent SDA 3A Anhydrous. MSDS indicate 4.8 weight percent methanol in the solvent. Methanol is also produced from a chemical reaction within the PMPU.

- 40 CFR Part 63, Subpart GGG – *National Emission Standards for Pharmaceuticals Production* is applicable to the Pharmaceutical X PMPU. Note: EPA has completed a Risk and Technology Review of this regulation.

- An existing scrubber is being used to control the emissions from the Pharmaceutical X PMPU as required by MACT GGG.

- This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of all pollutants are conditioned below de minimis levels.

- This installation is located in the City of St. Louis, a nonattainment area for the 8-hour ozone standard and the $PM_{2.5}$ standard and an attainment area for all other criteria pollutants.

- This installation is on the List of Named Installations found in 10 CSR 10-6.020(3)(B), Table 2 Item 20 – chemical process plants. The installation's major source level is 100 tons per year and fugitive emissions are counted toward major source applicability.

- Ambient air quality modeling was not performed since potential emissions of the application are below de minimis levels.

- Emissions testing is not required for the equipment by this permit. The scrubber was previously tested in August of 2001 and demonstrated 98.51% control efficiency. MACT GGG contains monitoring requirements sufficient to demonstrate proper operation of the control device. As Special Condition 1 limits the use of the equipment exclusively to the production of Pharmaceutical X, there would be no periods of time during which MACT GGG was not applicable to the equipment.

- The installation is required to update their Part 70 Operating Permit application, Project 1997-05-009, to include EP-1820, EP-1821, and EP-1822 within one year of equipment startup.

- Approval of this permit is recommended with special conditions.

INSTALLATION DESCRIPTION

Mallinckrodt LLC is an existing major source for both construction and operating permits. A Part 70 operating permit application, Project 1997-05-009, was received by the Air Pollution Control Program on May 13, 1997 and is still under review.

Mallinckrodt LLC manufactures a range of pharmaceutical, imaging, and respiratory products using an assortment of raw materials within the city limits of the City of St. Louis.

The following New Source Review permits have been issued to Mallinckrodt LLC by the City of St. Louis' Air Pollution Control Program.

Table 1: City of St. Louis Permit History

Permit Number	Description
94-10-107	Install two vents in building 510 where various maintenance activities occur such as welding, cutting, grinding, etc.
94-11-123	Building 200W
95-01-005	Install 20,000 gal wastewater neutralization tank and two 50,000 gal wastewater spill tanks
95-06-082SC	Building 97 pharmaceutical production modifications
95-07-089	Install emergency generator in Building Z
95-09-112A	Manufacture triiodamide and pharmaceutical intermediate 104 in Building 507
96-05-044	Install emergency generator near Building 62
97-01-055	Install DMAC Tank 520
97-04-030	Building X modifications
97-05-041	Install potassium chloride production facility in Building 3E
97-08-087A	Addition of Micro Mill #3, Gram Filling Machine, Vac-U-Max, Stokes Granulator, two Drum Blenders, and Fitz Mill #3 in Building 5
98-12-079SC	Increase peptide production in Buildings 96, 98, and 99
98-12-079SC PM	Addition of pilot scale pharmaceutical production Buildings 96, 98, and 99
98-12-079SC PM2	Addition of chloroform to allowable HAPs listed in Buildings 96 and 98
98-12-079SC PM3	Buildings 96 and 98 emission limit increases
98-12-079SC PMA	Amendment to 98-12-079SC PM3
98-12-079SC PM4	Addition of hexane to allowable HAPs

99-02-12SC	Buildings 6 and 7 toluene increase from extraction batches
99-02-013T	Water based pilot study
99-02-015	DMSO Bulk Transfer Operation
99-04-028	Buildings 6 and 7 modifications
99-10-073PM	Buildings 504 and 505 revisions to alternative synthesis of loversol
99-10-073	Loversol synthesis
99-11-075SC	Building 235 expansion
99-11-078	Construction of Building 260
00-02-007	Recordkeeping requirements for equipment leaks in Building 97
00-03-013A	Equipment modification to 95-06-082SC
00-03-015A	Process equipment change in Building 250
00-04-017A	Additional equipment modifications to 95-06-082SC
00-05-023	Blending various inorganic products in Building 3E
00-05-024A	Equipment modification in Building 200W
00-05-029	Install a 250 kW emergency generator in Building 260
00-10-047PM	Increase tank throughputs in 97-02-008
00-12-048	Pharmaceutical effluent guideline compliance project
01-07-023SC	Building 504 modifications
01-09-026F	Inorganic drug chemical complex in Buildings 222 and 223
01-09-026F PM	Modification of 01-09-026F
01-09-027	Installation of thermal oxidizer system, wastewater collection and treatment systems
01-09-027PM	Modification of 01-09-027
01-09-027PM1	Equipment list revision
01-09-027PM2	Equipment list revisions for Buildings 504 and 97
01-09-027PM3	Equipment list revisions to Plant 6
01-09-027PM4	Equipment list revisions to Plant 5
01-09-027PM5	Equipment list revisions to Buildings 6 and 7
02-02-007	Install a pharmaceutical/inorganic salt drying operation in Building 502
02-02-008PM	Install bulk storage tanks and a diesel engine
02-06-013	Addition of auger packer and sifter in Building X
03-01-002	Consolidation of SR00.015 and 95-07-087
03-01-002PM	Modification of 03-01-002
04-05-010	Install Tank 500
04-05-010A	Amendment to increase throughput
04-07-014T	Two diesel fueled temporary emergency generators
SR05.030	Building X
06-02-003	New tanks and scrubber in Building 260
09-06-015	Install three 575 HP diesel engine air compressors

The following New Source Review permits have been issued to Mallinckrodt LLC by the Missouri Air Pollution Control Program.

Table 2: Missouri Air Pollution Control Program Permit History

Permit Number	Description
032007-004	Install a 2.7 MMBtu/hr diesel engine air compressor

PROJECT DESCRIPTION

Mallinckrodt LLC has applied for the authority to construct EP-1820 BF-030 SS 2.25 m^2 Belt Filter, EP-1821 VP-837 (3) 50 gallon Filtrate Receivers and Vacuum Pump, and EP-1822 T-032 750 gallon Aqueous Slurry Tank. The new equipment and existing equipment in Building 260 will be part of a Pharmaceutical X PMPU. The

Pharmaceutical X PMPU operates in batches. The largest single batch of Pharmaceutical X that Mallinckrodt LLC will be able to produce with the new PMPU weighs 2,022 pounds and has a batch processing time of 2.3 days.

The Pharmaceutical X PMPU essentially has three parts: the Pharmaceutical X base, the crude Pharmaceutical X, and the purified Pharmaceutical X.

The Pharmaceutical X base process begins with an oxidation reaction which forms the methanol. Approximately 100 kilograms of methanol is produced in each batch. The volatile process contents at this stage in the process are primarily water and acetic acid. At this point, there is no ethanol in the process. Methanol is ~3% of the volatile components, and it is the most volatile component. This composition is relatively typical throughout this part of the process.

The crude Pharmaceutical X part of the process is mostly conducted in an aqueous environment. There are trace amounts of methanol carried into this step with the Pharmaceutical X base. There is also the final wash of the crude Pharmaceutical X with ethanol (denatured with 5% methanol). This is the first introduction of ethanol into the process.

The purified Pharmaceutical X part of the process is conducted in a solution of ethanol (~88%), methanol (~5%), and water (~7%). There is a second crop recovery step included in this part of the process that involves distillation and condensation of the ethanol.

EMISSIONS/CONTROLS EVALUATION

Emissions are based upon chemical analysis of lab-scale Pharmaceutical X production. At a production rate of 2,022 pounds per batch, each batch would emit a maximum of 12.70 pounds of VOC and 6.37 pounds of HAP (methanol). Emission calculations were performed using SuperPro Designer software. SuperPro Designer uses methodologies consistent with EPA guidelines. Emissions are routed to a scrubber, the control efficiency used within project calculations was 98%. With a batch processing time of 2.3 days, Mallinckrodt LLC will be able to produce a maximum of 159 batches per year.

If Mallincrodt LLC is able to improve the efficiency of the Pharmaceutical X production process in the future such that the batch processing time decreases or the maximum batch weight increases, Mallinckrodt LLC shall expediently amend this permit to reflect the maximum production rate.

If after achieving full-scale production of Pharmaceutical X Mallinckrodt LLC determines that a single batch contains greater quantities of VOC or HAP than evaluated by this permit, Mallincrodt LLC shall amend expediently amend this permit to reflect the maximum VOC and HAP quantities per batch.

Potential emissions of the project are below the insignificant emission exemption levels in 10 CSR 10-6.060(3)(A)3.A based exclusively on the production of Pharmaceutical X. Production of other pharmaceuticals would result in higher emissions; therefore, a

permit was required. Mallinckrodt LLC did not provide emissions calculations for the production of any other pharmaceutical; therefore, Special Condition 1 limits the use of the new equipment exclusively to the production of Pharmaceutical X. Mallinckrodt LLC may request to remove or revise Special Condition 1. Any request for removal or revision should contain potential emissions calculations for other pharmaceuticals Mallinckrodt LLC proposes to produce with the equipment.

The following table provides an emissions summary for this project. Existing potential emissions from the installation are unknown. Potential emissions of the project are below the PSD significance levels; therefore, a PSD permit would not have been required. Existing actual emissions were taken from the installation's 2012 EIQ. Potential emissions of the application represent the potential of the entire Pharmaceutical X PMPU (including both new and existing/modified equipment), assuming continuous operation (8,760 hours per year).

Table 3: Emissions Summary (tons per year)

Pollutant	Regulatory *De Minimis* Levels	Existing Potential Emissions	Existing Actual Emissions (2013 EIQ)	Conditioned Potential Emissions of the Application
PM	25.0	N/D	N/A	N/A
PM_{10}	15.0	N/D	13.09	N/A
$PM_{2.5}$	10.0	N/D	13.09	N/A
SO_x	40.0	N/D	5.88	N/A
NO_x	40.0	N/D	32.89	N/A
VOC	40.0	N/D	35.45	0.02
CO	100.0	N/D	22.04	N/A
GHG (CO_2e)	75,000 / 100,000	N/D	N/A	N/A
HAPs	25.0	N/D	6.87	0.01
Methanol (67-56-1)	10.0	N/D	3.73	0.01

N/A = Not Applicable; N/D = Not Determined

Project HAP emissions are subject to MACT GGG for which EPA has completed a Risk and Technology Review; therefore, Missouri's HAP modeling program is not applicable.

PERMIT RULE APPLICABILITY

This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060 *Construction Permits Required*. Potential emissions of all pollutants are below de minimis levels.

APPLICABLE REQUIREMENTS

Mallinckrodt LLC shall comply with the following applicable requirements. The Missouri Air Conservation Laws and Regulations should be consulted for specific record keeping, monitoring, and reporting requirements. Compliance with these emission standards, based on information submitted in the application, has been verified at the time this application was approved.

GENERAL REQUIREMENTS

- 10 CSR 10-6.065 *Operating Permits*
- 10 CSR 10-6.110 *Submission of Emission Data, Emission Fees and Process Information*
- 10 CSR 10-6.165 *Restriction of Emission of Odors*
- 10 CSR 10-6.170 *Restriction of Particulate Matter to the Ambient Air Beyond the Premises of Origin*
- 10 CSR 10-6.220 *Restriction of Emission of Visible Air Contaminants*

SPECIFIC REQUIREMENTS

- 10 CSR 10-5.350 *Control of Emissions From Manufacture of Synthesized Pharmaceutical Products*
- 10 CSR 10-5.540 *Control of Emissions From Batch Process Operations*
- 10 CSR 10-6.075 *Maximum Achievable Control Technology Regulations*
    - 40 CFR Part 63, Subpart GGG – *National Emission Standards for Pharmaceuticals Production*

STAFF RECOMMENDATION

On the basis of this review conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060 *Construction Permits Required*, I recommend this permit be granted with special conditions.

_____ _____

Alana L. Rugen, P.E. Date
New Source Review Unit

PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated March 19, 2014, received March 20, 2014, designating Mallinckrodt LLC as the owner and operator of the installation.

APPENDIX A

Abbreviations and Acronyms

%.....percent
ºF .....degrees Fahrenheit
acfm.....actual cubic feet per minute
BACT.....Best Available Control Technology
BMPs.....Best Management Practices
Btu.....British thermal unit
CAM.....Compliance Assurance Monitoring
CAS .....Chemical Abstracts Service
CEMS.....Continuous Emission Monitor System
CFR.....Code of Federal Regulations
CO.....carbon monoxide
CO_2.....carbon dioxide
CO_2e.....carbon dioxide equivalent
COMS .....Continuous Opacity Monitoring System
CSR .....Code of State Regulations
dscf.....dry standard cubic feet
EIQ.....Emission Inventory Questionnaire
EP .....Emission Point
EPA.....Environmental Protection Agency
EU.....Emission Unit
fps.....feet per second
ft .....feet
GACT.....Generally Available Control Technology
GHG.....Greenhouse Gas
gpm .....gallons per minute
gr .....grains
GWP .....Global Warming Potential
HAP .....Hazardous Air Pollutant
hr .....hour
hp.....horsepower
lb.....pound
lbs/hr .....pounds per hour
MACT.....Maximum Achievable Control Technology
$\mu g/m^3$ .....micrograms per cubic meter
m/s.....meters per second
Mgal.....1,000 gallons
MW .....megawatt
MHDR.....maximum hourly design rate
MMBtu....Million British thermal units
MMCF.....million cubic feet
MSDS .....Material Safety Data Sheet
NAAQS...National Ambient Air Quality Standards
NESHAPs .....National Emissions Standards for Hazardous Air Pollutants
NO_x.....nitrogen oxides
NSPS.....New Source Performance Standards
NSR .....New Source Review
PM .....particulate matter
$PM_{2.5}$.....particulate matter less than 2.5 microns in aerodynamic diameter
PM_{10} .....particulate matter less than 10 microns in aerodynamic diameter
PMPU .....Pharmaceutical Manufacturing Process Unit
ppm .....parts per million
PSD .....Prevention of Significant Deterioration
PTE.....potential to emit
RACT.....Reasonable Available Control Technology
RAL .....Risk Assessment Level
SCC .....Source Classification Code
scfm .....standard cubic feet per minute
SIC.....Standard Industrial Classification
SIP.....State Implementation Plan
SMAL.....Screening Model Action Levels
SO_x.....sulfur oxides
SO_2.....sulfur dioxide
tph .....tons per hour
tpy .....tons per year
VMT .....vehicle miles traveled
VOC.....Volatile Organic Compound

Mr. Dexter Evans
Senior Site Director
Mallinckrodt LLC
3600 North Second Street
St. Louis, MO 63147

RE: New Source Review Permit - Project Number: 2014-03-034

Dear Mr. Evans:

Enclosed with this letter is your permit to construct. Please study it carefully and refer to Appendix A for a list of common abbreviations and acronyms used in the permit. Also, note the special condition on the accompanying pages. The document entitled, "Review of Application for Authority to Construct," is part of the permit and should be kept with this permit in your files. Operation in accordance with these conditions, your new source review permit application, and amending your operating permit application is necessary for continued compliance. The reverse side of your permit certificate has important information concerning standard permit conditions and your rights and obligations under the laws and regulations of the State of Missouri.

If you have any questions regarding this permit, please do not hesitate to contact Alana Rugen, at the Department of Natural Resources' Air Pollution Control Program, P.O. Box 176, Jefferson City, MO 65102 or at (573) 751-4817. Thank you for your attention to this matter.

Sincerely,

AIR POLLUTION CONTROL PROGRAM

Susan Heckenkamp
New Source Review Unit Chief

SH:arl

Enclosures

c: St. Louis Regional Office
PAMS File: 2014-03-034

Permit Number: