



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: **022016-012**

Project Number: 2015-09-029
Installation Number: 510-0017

Parent Company: Mallinckrodt LLC

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

Installation Name: Mallinckrodt LLC

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

Location Information: St. Louis City, Land Grant

Application for Authority to Construct was made for:
an expansion to bldg. 260 for the more efficient production of pharmaceutical products. Three products will be manufactured in this expansion: Product A, Product B, and Product C. This review was conducted in accordance with Section (5), 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.

Steckenkamp for

Prepared by
Randy Raymond
New Source Review Unit

Kendall B. Halo for

Director or Designee
Department of Natural Resources

FEB 23 2016

Effective Date

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 startup 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 paragraph (12)(A)10. "Conditions required by permitting authority."

Mallinckrodt LLC
St. Louis City, Land Grant

1. Scrubber, 260-CD-01, Emission Limitation
 - A. Title 40, Part 63, Subpart GGG—*National Emission Standards for Pharmaceuticals Production* [§63.1254] Standards: Process vents.
 - (a) Existing sources. For each process, the owner or operator of an existing affected source must comply with the requirements in paragraphs (a)(1) and (3) of this section or paragraphs (a)(2) and (3) of this section. Initial compliance with the required emission limits or reductions in paragraphs (a)(1) through (3) of this section is demonstrated in accordance with the initial compliance procedures described in §63.1257(d), and continuous compliance is demonstrated in accordance with the monitoring requirements described in §63.1258.
 - (1) Process-based emission reduction requirement.
 - (i) Uncontrolled HAP emissions from the sum of all process vents within a process shall be reduced by **93 percent or greater by weight**. Notification of changes in the compliance method shall be reported according to the procedures in §63.1260(h).
 - B. Mallinckrodt LLC shall control emissions from *Table 3 Project Unit Listing* (with the exception of EP7012, Drum Filling Station) using scrubber, SC-090 (260-CD-01) as specified in the permit application.
 - C. The scrubber shall be operated and maintained in accordance with the manufacturer's specifications. Mallinckrodt LLC shall maintain a copy of the scrubber manufacturer's specifications on site.
 - D. Mallinckrodt LLC shall insure that at least an eight and a half (8.5) gallons per minute flow rate of liquid is maintained in the scrubber, until an appropriate flow rate can be established through performance testing.
 - E. Mallinckrodt LLC shall monitor and record the gallons per minute flow rate of the scrubber as their method of compliance and in accordance with Table 1.
 - F. Mallinckrodt LLC shall comply with the requirements of §63.1258 Monitoring Requirements.

SPECIAL CONDITIONS:

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

(a) The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in this section. During the initial compliance demonstration, maximum or minimum operating parameter levels, as appropriate, shall be established for emission sources that will indicate the source is in compliance. Test data, calculations, or information from the evaluation of the control device design shall be used to establish the operating parameter level.

(b) *Monitoring for control devices*—(1) *Parameters to monitor*. Except as specified in paragraph (b)(1)(i) of this section, for each control device, the owner or operator shall install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard. Monitoring parameters are specified for control scenarios in Table 4 of this subpart and in paragraphs (b)(1)(ii) through (xi) of this section.

(i) *Periodic verification*. For control devices that control vent streams totaling less than 1 ton per year HAP emissions, before control, monitoring shall consist of a daily verification that the device is operating properly. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed and may include the daily measurements of the parameters described in (b)(1)(ii) through (x) of this section. This demonstration shall be included in the Precompliance report, to be submitted 6 months prior to the compliance date of the standard.

(ii) *Scrubbers*. For affected sources using liquid scrubbers, the owner or operator shall establish a minimum scrubber liquid flow rate or pressure drop as a site-specific operating parameter which must be measured and recorded every 15 minutes during the period in which the scrubber is functioning in achieving the HAP removal required by this subpart. If the scrubber uses a caustic solution¹ to remove acid emissions, the owner or operator shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter which must be monitored at least once a day. As an alternative to measuring pH, you may elect to continuously monitor the caustic strength of the scrubber effluent. The minimum scrubber flowrate or pressure drop shall be based on the conditions anticipated under worst-case conditions, as defined in §63.1257(b)(8)(i).

(A) The monitoring device used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ± 10 percent of the maximum pressure drop measured.

¹ Mallinckrodt LLC uses once-through city water as scrubber effluent, therefore no pH monitoring is required.

SPECIAL CONDITIONS:

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

(B) The monitoring device used for measurement of scrubber liquid flowrate shall be certified by the manufacturer to be accurate within ± 10 percent of the design scrubber liquid flowrate.

(C) The monitoring device shall be calibrated annually.

Table 1 (Table 4 to Subpart GGG of Part 63)—Monitoring Requirements for Control Devices²

Control device	Monitoring equipment required	Parameters to be monitored	Frequency
All control devices	1. Flow indicator installed at all bypass lines to the atmosphere and equipped with continuous recorder <i>or</i>	1. Presence of flow diverted from the control device to the atmosphere <i>or</i>	Hourly records of whether the flow indicator was operating and whether a diversion was detected at any time during each hour.
	2. Valves sealed closed with car-seal or lock-and-key configuration	2. Monthly inspections of sealed valves	Monthly.
Scrubber	Liquid flow rate or pressure drop mounting device. Also a pH monitor if the scrubber is used to control acid emissions	1. Liquid flow rate into or out of the scrubber or the pressure drop across the scrubber	1. Every 15 minutes.
		2. pH of effluent scrubber liquid ³	2. Once a day.

G. Mallinckrodt LLC shall comply with the requirements of §63.1259 Recordkeeping requirements.

2. Record Keeping and Reporting Requirements

A. Mallinckrodt LLC shall maintain all records required by this permit for not less than five years and shall make them available immediately to any Missouri Department of Natural Resources' personnel upon request.

² As an alternative to the monitoring requirements specified in this table, the owner or operator may use a CEM meeting the requirements of Performance Specifications 8 or 9 of appendix B of part 60 to monitor TOC every 15 minutes.

³ If the scrubber uses a caustic solution to remove acid emissions, the owner or operator shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter which must be monitored at least once a day. As an alternative to measuring pH, you may elect to continuously monitor the caustic strength of the scrubber effluent. The minimum scrubber flowrate or pressure drop shall be based on the conditions anticipated under worst-case conditions, as defined in §63.1257(b)(8)(i).

SPECIAL CONDITIONS:

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

- B. Mallinckrodt LLC shall report to the Air Pollution Control Program's Compliance/Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than 10 days after the end of the month during which any record required by this permit show an exceedance of a limitation imposed by this permit.
3. Performance Testing
- A. The appropriate testing procedures shall be used to determine compliance with Title 40, Part 63, Subpart GGG—National Emission Standards for Pharmaceuticals Production §63.1257 *Test methods and compliance procedures* (the control efficiency of scrubber 260-CD-01 for methanol).
 - B. These tests shall be performed within 60 days after achieving the maximum production rate of the installation, but not later than 180 days after initial start-up for commercial operation and shall be conducted in accordance with the Stack Test Procedures outlined in Special Condition 3.A.
 - C. A completed Proposed Test Plan Form (enclosed) must be submitted to the Air Pollution Control Program 30 days prior to the proposed test date so that the Air Pollution Control Program may arrange a pretest meeting, if necessary, and assure that the test date is acceptable for an observer to be present. The Proposed Test Plan may serve the purpose of notification and must be approved⁴ by the Director prior to conducting the required emission testing.
 - D. Two copies of a written report of the performance test results shall be submitted to the Director within 60 days of completion of any required testing. The report must include legible copies of the raw data sheets, analytical instrument laboratory data, and complete sample calculations from the required U.S. EPA Method for at least one sample run.
 - E. The test report is to fully account for all operational and emission parameters addressed both in the permit conditions as well as in any other applicable state or federal rules or regulations.

⁴ In particular, agreement must be reached and approved between Mallinckrodt LLC and the Director, or their designee.

REVIEW OF APPLICATION FOR AUTHORITY TO CONSTRUCT AND OPERATE
SECTION (5) REVIEW

Project Number: 2015-09-029
Installation ID Number: 510-0017
Permit Number:

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

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

St. Louis City, Land Grant

REVIEW SUMMARY

- Mallinckrodt LLC has applied for an expansion to bldg. 260 for the more efficient production of pharmaceutical products. Three products will be manufactured in this expansion: Product A, Product B, and Product C.
- The application was deemed complete on September 14, 2015.
- HAP emissions are expected from the proposed equipment. Methanol is the HAP emitted from these process.
- None of the NESHAPs apply to this installation. The MACT standard, 40 CFR Part 63, Subpart GGG—*National Emission Standards for Pharmaceuticals Production* applies to this project.
- All emissions from manufacturing will be routed to an existing VOC Scrubber in Bldg. 260, 260-CD-01, with the exception of the drum filling operation.
- This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions (after air pollution control equipment is considered) of VOCs are conditioned below the *de minimis* levels.
- This installation is located in St. Louis City, 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 (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 required for the scrubber, 260-CD-01.
- A Part 70 Operating Permit application is currently being reviewed. This project is required to be incorporated into the application as a revision.
- Approval of this permit is recommended with special conditions.

INSTALLATION DESCRIPTION

Mallinckrodt LLC owns and operates a manufacturing plant in downtown St. Louis, Missouri. The plant is located in an urban industrial area, zoned and developed for industrial use. Mallinckrodt has owned the site and has operated chemical manufacturing processes on the site since 1867. The St. Louis Plant contains more than 50 manufacturing and support buildings in an area of approximately twelve city blocks over 43 acres. Support operations include maintenance shops, laboratories, warehouses, steam boilers, wastewater and air treatment operations, and other storage areas.

Mallinckrodt's current products include a full line of bulk pharmaceuticals including opiates and synthetic narcotics, diagnostic medical imaging products, peptides used for various therapeutics, stearates and a variety of specialty inorganics.

To comply with 40 CFR Part 63 Subpart GGG, Mallinckrodt installed control equipment and revised several existing permits of affected source operations. The affected source (equipment, activities within a single contiguous area) operations consist of operations which were subject to the control strategies and emissions limitations of Subpart GGG and occurred in Buildings 97, 6/7, 5, 502, 250, 260, 97 Tech Center, 235, 200, 504, 505, 507, 512, 514 & 516, Tank Farms, 250 Lab, 96, 98 & 99, 222 & 223, X, Utilities & Maintenance, Emergency Generators. Mallinckrodt installed a main and standby thermal oxidizer (TOX) to combust HAP emissions from process operations and wastewater steam strippers that were also required for MACT compliance. In addition, the site utilizes other control equipment such as dust collectors and wet scrubbers throughout the plant to minimize emissions to the environment.

The Air Pollution Control Program has reviewed the following New Source Review projects:

Table 2: Project History

Project ID	Permit Number	Start Date	Complete Date	Description
EX5100017004	0682-EPA	06/17/82	06/17/82	Unit 6 Coal and Oil
EX5100017005	BANK	08/06/91	12/29/93	
EX199705009	OP	05/13/97		Chemical manufacture
EX199812094	95-09-112A	12/23/98	01/22/99	Pharmaceutical Intermediate Mfg.

Project ID	Permit Number	Start Date	Complete Date	Description
EX199903092	98-12-079S	03/17/99	04/16/99	Peptide production increase
EX199904044	99-02-013T	04/12/99	05/12/99	water-based pilot study
EX199904045	99-02-012S	04/12/99	05/13/99	Increase toluene extraction batches
EX199906061	99-04-028	06/16/99	07/16/99	Chemical manufacture
EX199907051	99-02-015	07/16/99	08/15/99	DMSO transfer operation
EX200003040	00-02-007	03/09/00	04/10/00	Record keeping
EX200003087	00-03-013A	03/23/00	04/22/00	Equipment Change
EX200004100	00-04-017A	04/24/00	05/24/00	Pilot lab unit
EX200005027	99-11-075S	05/05/00	06/04/00	Building expansion
EX200005029	00-03-015A	05/05/00	06/04/00	Change process equipment
EX200006009	00-05-023	06/02/00	07/02/00	Product blending
EX200007011	00-05-024A	06/30/00	07/30/00	Process equipment change
EX200007034	00-05-029	07/10/00	08/09/00	Emergency generator
EX200007035	99-11-075S	07/10/00	08/09/00	Building Expansion
EX200007099	99-10-073	07/26/00	08/25/00	Loversol Synthesis
EX200010093	99-11-078	10/26/00	11/26/00	Production building
EX200012005	00-10-047	12/04/00	01/03/01	Tank Throughput
AP200107057	00-12-048	07/18/01	08/17/01	Effluent guideline project
AP200110033	99-10-073PM	10/01/01	10/31/01	Term Revision
AP200110048	01-07-023SC	10/15/01	11/14/01	Imaging and Pharmaceuticals
AP200201018		12/31/01	01/31/02	Building 222 Complex
AP200203012		02/27/02	03/29/02	Draft Re-submittal
AP200203149		03/29/02	06/27/06	Pollution Control \$29,444,069.60
AP200203162	98-12-079SC PM	03/29/02	04/28/02	Pilot Scale Production
AP200204059	01-09-026F	04/05/02	05/05/02	Objection Response
AP200206073	02-02-008PM	06/14/02	07/19/02	Tank Throughput
AP200206112		06/24/02	09/23/04	Subparts DDDDD & FFFF
AP200207114	01-09-027	07/22/02	08/30/02	Thermal oxidizer
AP200208004		08/01/02	08/30/02	Local Agency - Nitrogen Generation
AP200208081	02-02-007	08/07/02	08/30/02	Salt Drying operation
AP200209022	02-06-013	09/03/02	10/03/02	Auger Packer
AP200211156	01-09-026F	11/15/02	12/07/02	Scrubber & Baghouse
AP200307020	03-01-002	07/03/03	07/29/03	Consolidate mills & granulators
AP200402086	98-12-079SC	02/19/04	03/19/04	Add Product
AP200403131	98-12-079SC PM2	03/24/04	04/21/04	Add HAP
AP200406091		06/25/04	07/07/04	Withdraw 4 permits
AP200408103	04-07-014T	08/30/04	09/03/04	Generators
AP200409063	01-09-027PM	09/22/04	10/01/04	Thermal oxidizer modifications

Project ID	Permit Number	Start Date	Complete Date	Description
AP200410020	02-02-008PM	10/12/04	12/20/05	Tanks
AP200411003	01-09-027PM	11/01/04	12/20/05	Thermal oxidizer
AP200411004	97-08-087A	11/01/04	12/20/05	Mills and blenders
AP200411092	01-09-027PM	11/19/04	12/20/05	Equipment List
AP200411093	97-05-041	11/19/04	12/20/05	Terminate permit
AP200412057	04-05-010	12/10/04	12/20/05	Tanks/Engine
AP200412060	01-09-027PM	12/15/04	12/20/05	Equipment list revisions
AP200502025	01-09-027PM	01/24/05	12/20/05	Equipment list revision 3
AP200502051		02/14/05	03/23/05	Boiler Operation-applicability
AP200508065	01-09-027PM	08/29/05	09/28/05	Waste Tanks
AP200510062		10/26/05	11/22/05	Wording changes
AP200510063		10/26/05	11/22/05	Emission limit increases
AP200511083	04-05-010A	11/09/05	12/09/05	Tank throughput changes
AP200512008	01-09-027PM	12/01/05	01/04/06	Equipment list revision
AP200601014	98-12-079SC	01/03/06	01/10/06	Modify Condition
AP200602083	06-02-003	02/23/06	03/15/06	New tanks and scrubber
AP200605049	03-01-002PM	05/17/06	06/07/06	Limit, configuration changes
AP200605050	98-12-079SC PM4	05/17/06	06/07/06	Hexane and HAPs
AP200609078	01-09-027PM	09/27/06	10/26/06	Equipment list revision
AP200610009	01-09-027PM	10/02/06	11/13/08	NOx emission increase submittal
AP200610010		10/02/06	03/01/07	Add toluene to HAPs
AP200611098	032007-004	11/22/06	03/15/07	Throughput limits
AP200709014		09/10/07	09/18/07	Cooling Tower
AP200906052	09-06-015	06/19/09	06/23/09	Diesel Air Compressors
AP200911039		11/18/09		VOC PAL
AP201002083	10-01-001	02/24/10	02/25/10	Natural Gas Boiler
AP201103094	10-01-001A	03/25/11	04/12/11	Extension
AP201105038		05/17/11	05/17/11	Boilers and Tower
AP201106018	99-11-078	06/08/11	06/16/11	Dust Collector
AP201402027	092014-001	02/14/14	09/02/14	Dryer
AP201403034	072014-004	03/20/14	07/15/14	New Equipment
AP201403042		03/20/14	07/15/14	Confidentiality for 2014-03-034
AP201407072	092014-001	07/28/14	09/02/14	Confidentiality for 2014-02-027

PROJECT DESCRIPTION

Mallinckrodt Pharmaceuticals (St. Louis Plant) is expanding Building 260 to accommodate more efficient production of pharmaceutical products. Three potential

products will be manufactured in this expansion of Building 260: Product A, Product B, and Product C.

The following table lists the equipment that will be utilized (in different configurations) to manufacture the products:

Table 3 Project Unit Listing

POINT NO.	POINT DESCRIPTION
EP 7002	T-331 Dissolver Tank
EP 7003	T-333 Crystallizer
EP 7004	T-334 Crystallizer
EP 7005	T-335 Crystallizer
EP 7006	T-337 Centrifuge Feed Tank
EP 7007	T-338 Centrifuge
EP 7008	T-339 Mother Liquor Stripper Tank
EP 7009	T-340 Distillate Tank
EP 7010	T-341 Recovered Alcohol Tank
EP 7011	T-342 Acid Make-up Tank
EP 7012	Drum Filling Station

Diagrams of the various equipment configurations are considered confidential business information. Please refer to Appendix 1 to this review for the locational information within the St. Louis Plant.

EMISSIONS/CONTROLS EVALUATION

Emission calculations for this project are included in Appendix 2. Emissions from this project are subject to Part 63, Subpart GGG. All emissions from manufacturing will be routed to an existing VOC scrubber in Building 260, 260-CD-01, with the exception of the drum filling operation.

Emission estimates from the drum filling are based on a conservative estimate assuming 50% of solvent in the wet cake is evaporated during the operation. Of the 50% solvent evaporated, 50% of those emissions are assumed to be recaptured by the vacuum pulling from the scrubber header system. All other emissions were estimated using SuperPro Designer, which uses formulas from "OAQPS, Control of Volatile

Organic Emissions from Manufacture of Synthesized Pharmaceutical Products, EPA-450/2-78-029, December 1978" and "OAQPS, Control of Volatile Organic Compound Emissions from Batch Processes, EPA-453/R-94-020, February 1994".

Emission estimates in Appendix 2 are based on the maximum batches of a single product that could be manufactured in 365 days. Emissions are produced from the use of 3A Alcohol (the SDS was included with application), which contains approximately 95% Ethanol and 5% Methanol, by weight.

The worst case scenario for HAP emissions (methanol) was provided by the production of Product C with 0.37 tpy MeOH, after controls. The worst case scenario for Total VOC emissions was provided by the production of Product C with 8.31 tpy EtOH/MeOH, after controls. Performance testing of the scrubber is required by 63.1257 of 40 CFR 63 Subpart GGG based on two items: the uncontrolled HAP emissions from the sum of all process vents within a process are changing sufficiently enough; and, the age the previous testing. The maximum number of batches of Product C that could be produced in 365 days was 144 batches. Included in the Product C emission estimate are the emissions of Product C Recovery, which at a maximum would be 24 batches in 365 days.

Using the emission estimates, the kilogram per batch emission rates and various configurations of equipment, and zero control efficiency for the scrubber and for drum loading, the following table sums up the number of batches that would have to be exceeded for any product to exceed the *de minimis* level thresholds:

Table 4 Number of Batches to Emit at *De minimis*

	Using the Maximum Emitting Segment	Using All the Segments at the same time
Number of batches Needed to hit 40 tons VOC	2749	364
Number of batches Needed to hit 10 tons of MeOH	864	1437

The following table provides an emissions summary for this project. Existing potential emissions were not determined, but will be done as a part of the upcoming Part 70 State Operating Permit review. This is acceptable based on the fact that Mallinckrodt LLC is being limited to the major modification threshold, to insure that this project is not a major modification at a major source. Existing actual emissions were taken from the installation's 2014 MoEIS/EIQ annual submittal. Potential emissions of the application represent the potential of the products produced in the modified equipment, assuming maximum batch operation per year.

Table 5: Emissions Summary (tons per year, rounded to the nearest tenth ton)

Pollutant	Regulatory <i>De Minimis</i> Levels	Existing Actual Emissions (2014 EIQ)	Potential Emissions of the Application
PM	25.0	N/D	N/A
PM ₁₀	15.0	5.9	N/A
PM _{2.5}	10.0	5.9	N/A
SOx	40.0	3.0	N/A
NOx	40.0	13.1	N/A
VOC	40.0	21.9	14.6
CO	100.0	14.3	N/A
HAPs	10.0/25.0	7.2 ⁵	0.7

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

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 VOCs are conditioned 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

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

⁵ This value includes the amount of HAPs that are reported as VOC or PM₁₀, which is allowed under the annual reporting rule.

SPECIFIC REQUIREMENTS

- *Control of Emissions From Manufacture of Synthesized Pharmaceutical Products*, 10 CSR 10-5.350
- *MACT Regulations*, 10 CSR 10-6.075
Title 40: Protection of Environment
PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES
Subpart GGG—National Emission Standards for Pharmaceuticals Production

STAFF RECOMMENDATION

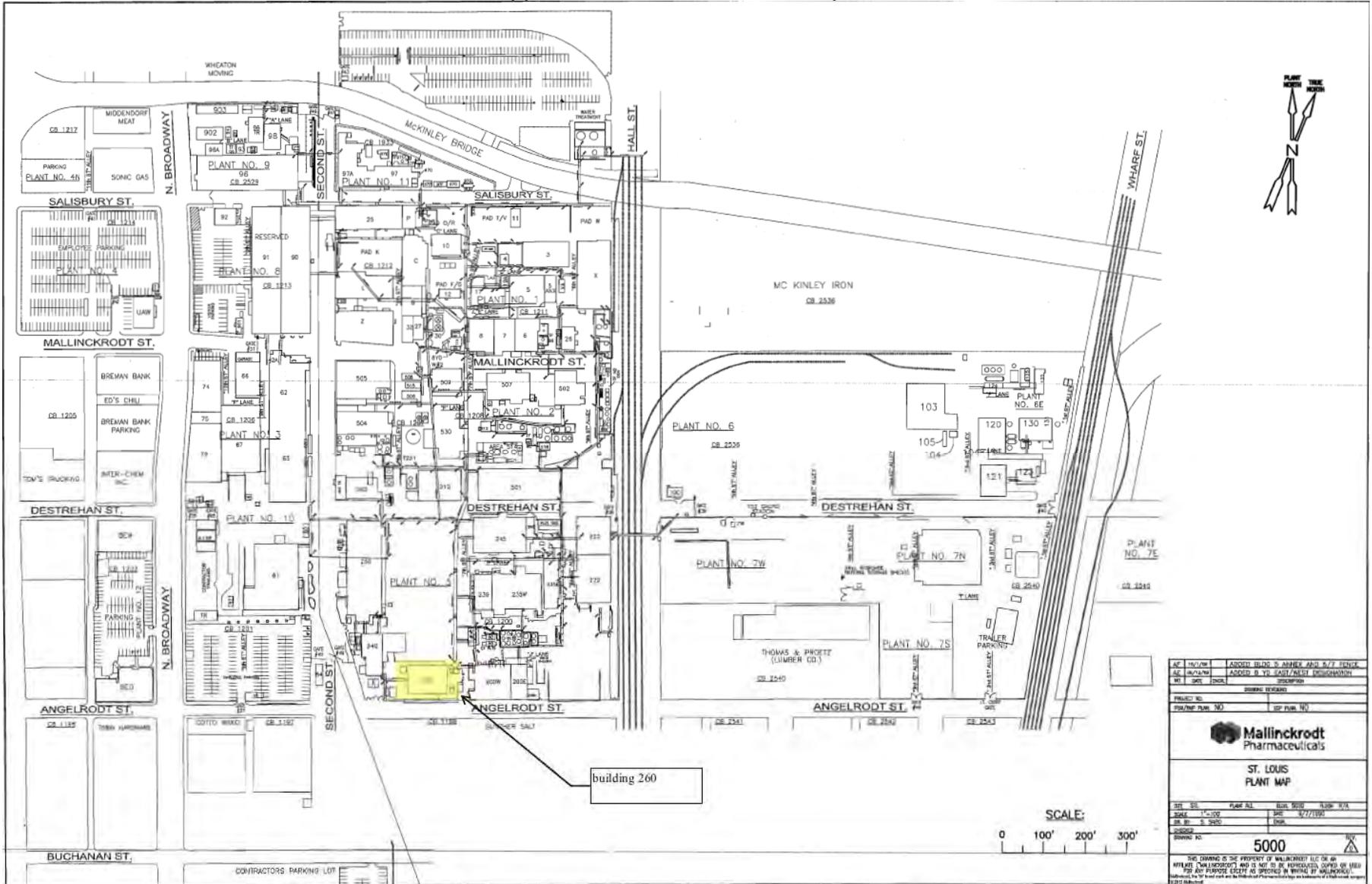
On the basis of this review conducted in accordance with Section (5), Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*, it is recommended that this permit be granted with special conditions.

PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated September 10, 2015, received September 14, 2015, designating Mallinckrodt LLC as the owner and operator of the installation.

Appendix 1 – St. Louis Plant Layout



AC	12/1/98	ADD'D BRDG. 2, 3, 4, 5, 6, 7, 7A, 7B, 7C, 7D, 7E, 7F, 7G, 7H, 7I, 7J, 7K, 7L, 7M, 7N, 7O, 7P, 7Q, 7R, 7S, 7T, 7U, 7V, 7W, 7X, 7Y, 7Z
AL	12/1/98	ADD'D B. TO EAST/WEST ENCLOSURE
MT	08/1/2004	REVISION
PROJECT NO.		00000000
DRAWING PLAN NO.		00 PLAN 00
ST. LOUIS PLANT MAP		
REV.	DATE	BY
01	12/1/98	DKA
02	08/1/2004	DKA
5000		
<small>THIS DRAWING IS THE PROPERTY OF MALLINCKRODT. IT IS NOT TO BE REPRODUCED, COPIED, OR USED FOR ANY PURPOSE EXCEPT AS SPECIFIED IN WRITING BY MALLINCKRODT. MALLINCKRODT AND ITS AFFILIATES ARE NOT RESPONSIBLE FOR ANY ERRORS OR OMISSIONS.</small>		

Appendix 2 – Summary Emissions Calculations from the Application
[continues for ten (10) pages]

PRODUCT B

Total Possible Batches Per One Year: 144

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-331	Dissolver	37.2	Methanol	0.03	4.32
		781.48	Ethanol	0.37	53.28
		818.68	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-333	Pan Crystallizer	41.1	Methanol	0.02	2.88
T-334		864.21	Ethanol	0.25	36
T-335		905.31	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-337	Centrifuge Feed Tank	39.27	Methanol	0.01	1.44
		826.26	Ethanol	0.2	28.8
		865.53	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
CF-138	Centrifuge	53.82	Methanol	0.01	1.44
		1131.94	Ethanol	0.2	28.8
		1185.76	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT B:

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
Drum Loading	Drum Loading	66.36	Ethanol	33.18	4777.92
		3.16	Methanol	1.58	227.52
		69.52	Total Kg		

The drumming calculations assume that 50% of the solvent in the wet cake is evaporated. The drumming station is right below the centrifuge and draws air back into the centrifuge to the Scrubber Header system . This calculation also assumes that only 50% of the emissions are captured by the header system.

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-339	ML Stripper	50.66	Methanol	0.02	2.88
		1084.93	Ethanol	0.33	47.52
		1135.59	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-340	Condensate Receiver	56.76	Methanol	0.02	2.88
		1112.64	Ethanol	0.23	33.12
		1169.4	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-341	Recovered Alcohol	59.19	Methanol	0.03	4.32
		1124.56	Ethanol	0.33	47.52
		1183.75	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT B:

		Conversion to Lbs	Conversion to Tons
Total Annual EtOH Emissions Uncontrolled (Kg)	5052.96	11139.75562	5.569877808
Total Annual MeOH Emissions Uncontrolled (Kg)	247.68	546.035328	0.273017664
Total Annual EtOH Emissions After Scrubber Control (Kg)	2439.576	5378.28925	2.689144625
Total Annual MeOH Emissions After Scrubber Control (Kg)	120.456	265.5572976	0.132778649

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT C:

Total Possible Batches Per One Year: 144

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-331	Dissolver	33.33	Methanol	0.03	4.32
		699.99	Ethanol	0.36	51.84
		733.32	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-333	Pan Crystallizer	36.78	Methanol	0.02	2.88
T-334		787.55	Ethanol	0.25	36
T-335		824.33	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-337	Centrifuge Feed Tank	67.9	Methanol	0.01	1.44
		1429.71	Ethanol	0.19	27.36
		1497.61	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
CF-138	Centrifuge	52.49	Methanol	0.01	1.44
		1104.26	Ethanol	0.19	27.36
		1156.75	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT C:

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
Drum Loading	Drum Loading	76.02	Ethanol	38.01	13683.6
		3.62	Methanol	1.81	651.6
		79.64	Total Kg		

The drumming calculations assume that 50% of the solvent in the wet cake is evaporated. The drumming station is right below the centrifuge and draws air back into the centrifuge to the Scrubber Header system . This calculation also assumes that only 50% of the emissions are captured by the header system.

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-339	ML Stripper	84.42	Methanol	0.02	2.88
		1776.5	Ethanol	0.31	44.64
		1860.92	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-340	Condensate Receiver	96.19	Methanol	0.02	2.88
		1943.73	Ethanol	0.22	31.68
		2039.92	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-341	Recovered Alcohol	125.94	Methanol	0.04	5.76
		2395.85	Ethanol	0.43	61.92
		2521.79	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT C:

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-339	ML Stripper	40.14	Methanol	0.03	0.72
		872.98	Ethanol	0.52	12.48
		913.12	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-340	Condensate Receiver	34.54	Methanol	0.01	0.24
		751.59	Ethanol	0.16	3.84
		786.13	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-337	Centrifuge Feed Tank	2.78	Methanol	0.002	0.048
		60.42	Ethanol	0.05	1.2
		63.2	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
CF-138	Centrifuge	2.78	Methanol	0.002	0.048
		60.4	Ethanol	0.05	1.2
		63.18	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT C:

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
Drum Loading	Drum Loading	0.1137	Ethanol	0.05685	1.3644
		0.0052	Methanol	0.0026	0.0624
		0.1189	Total Kg		

The drumming calculations assume that 50% of the solvent in the wet cake is evaporated. The drumming station is right below the centrifuge and draws air back into the centrifuge to the Scrubber Header system . This calculation also assumes that only 50% of the emissions are captured by the header system.

		Conversion to Lbs	Conversion to Tons
Total Annual EtOH Emissions Uncontrolled (Kg)	13984.4844	30830.19431	15.41509715
Total Annual MeOH Emissions Uncontrolled (Kg)	674.3184	1486.602345	0.743301172
Total Annual EtOH Emissions After Scrubber Control (Kg)	7199.58231	15872.19916	7.93609958
Total Annual MeOH Emissions After Scrubber Control (Kg)	332.4524568	732.9246863	0.366462343

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT A:

Total Possible Batches Per One Year: 360

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-331	Dissolver	50.43	Methanol	0.02	7.2
		958.13	Ethanol	0.19	68.4
		1008.56	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-333	Pan Crystallizer	57.43	Methanol	0.06	21.6
T-334		1100.63	Ethanol	0.43	154.8
T-335		1158.06	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-337	Centrifuge Feed Tank	57.43	Methanol	0.01	3.6
		1100.63	Ethanol	0.08	28.8
		1158.06	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
CF-138	Centrifuge	70.59	Methanol	0.01	3.6
		1350.67	Ethanol	0.09	32.4
		1421.26	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT A:

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
Drum Loading	Drum Loading	31.78	Ethanol	15.89	5720.4
		1.67	Methanol	0.835	300.6
		33.45	Total Kg		

The drumming calculations assume that 50% of the solvent in the wet cake is evaporated. The drumming station is right below the centrifuge and draws air back into the centrifuge to the Scrubber Header system . This calculation also assumes that only 50% of the emissions are captured by the header system.

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-339	ML Stripper	68.92	Methanol	0.01	3.6
		1318.89	Ethanol	0.13	46.8
		1387.81	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-340	Condensate Receiver	70.42	Methanol	0.02	7.2
		1347.23	Ethanol	0.23	82.8
		1417.65	Total Kg		

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-341	Recovered Alcohol	70.42	Methanol	0.02	7.2
		1347.23	Ethanol	0.23	82.8
		31.27	Water	NA	NA
		1448.92	Total Kg		

Appendix 2 – Summary Emissions Calculations from the Application
[continued]

PRODUCT A:

Unit	Description	Max. Mass Throughput (kg/batch)	Product	Air Emissions (kg/batch)	Potential Annual Emissions Uncontrolled (kg)
T-342	Acid Make Up	128.25	Ethanol	0.18	64.8
		6.75	Methanol	0.02	7.2
		135	Total Kg		

		Conversion to Lbs	Conversion to Tons
Total Annual EtOH Emissions Uncontrolled (Kg)	6282	13849.2972	6.9246486
Total Annual MeOH Emissions Uncontrolled (Kg)	361.8	797.62428	0.39881214
Total Annual EtOH Emissions After Scrubber Control (Kg)	3031.29	6682.781934	3.341390967
Total Annual MeOH Emissions After Scrubber Control (Kg)	160.875	354.665025	0.177332513

APPENDIX A

Abbreviations and Acronyms

%	percent	m/s	meters per second
°F	degrees Fahrenheit	Mgal	1,000 gallons
acfm	actual cubic feet per minute	MW	megawatt
BACT	Best Available Control Technology	MHDR	maximum hourly design rate
BMPs	Best Management Practices	MMBtu	Million British thermal units
Btu	British thermal unit	MMCF	million cubic feet
CAM	Compliance Assurance Monitoring	MSDS	Material Safety Data Sheet
CAS	Chemical Abstracts Service	NAAQS ...	National Ambient Air Quality Standards
CEMS	Continuous Emission Monitor System	NESHAPs	National Emissions Standards for Hazardous Air Pollutants
CFR	Code of Federal Regulations	NO_x	nitrogen oxides
CO	carbon monoxide	NSPS	New Source Performance Standards
CO₂	carbon dioxide	NSR	New Source Review
CO_{2e}	carbon dioxide equivalent	PM	particulate matter
COMS	Continuous Opacity Monitoring System	PM_{2.5}	particulate matter less than 2.5 microns in aerodynamic diameter
CSR	Code of State Regulations	PM₁₀	particulate matter less than 10 microns in aerodynamic diameter
dscf	dry standard cubic feet	ppm	parts per million
EQ	Emission Inventory Questionnaire	PSD	Prevention of Significant Deterioration
EP	Emission Point	PTE	potential to emit
EPA	Environmental Protection Agency	RACT	Reasonable Available Control Technology
EU	Emission Unit	RAL	Risk Assessment Level
fps	feet per second	SCC	Source Classification Code
ft	feet	scfm	standard cubic feet per minute
GACT	Generally Available Control Technology	SDS	Safety Data Sheet
GHG	Greenhouse Gas	SIC	Standard Industrial Classification
gpm	gallons per minute	SIP	State Implementation Plan
gr	grains	SMAL	Screening Model Action Levels
GWP	Global Warming Potential	SO_x	sulfur oxides
HAP	Hazardous Air Pollutant	SO₂	sulfur dioxide
hr	hour	tph	tons per hour
hp	horsepower	tpy	tons per year
lb	pound	VMT	vehicle miles traveled
lbs/hr	pounds per hour	VOC	Volatile Organic Compound
MACT	Maximum Achievable Control Technology		
µg/m³	micrograms per cubic meter		

Mr. Jonathan Eckles, CHMM
Principal EHS Engineer
Mallinckrodt LLC
3600 North Second Street
St. Louis, MO 63147

RE: New Source Review Permit - Project Number: 2015-09-029

Dear Mr. Eckles, CHMM:

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 conditions, if any, 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 with your amended operating permit 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 were adversely affected by this permit decision, you may be entitled to pursue an appeal before the administrative hearing commission pursuant to Sections 621.250 and 643.075.6 RSMo. To appeal, you must file a petition with the administrative hearing commission within thirty 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 administrative hearing commission, whose contact information is: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102, phone: 573-751-2422, fax: 573-751-5018, website: www.aa.mo.gov/ahc.

If you have any questions regarding this permit, please do not hesitate to contact Randy Raymond, 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:rrl

Enclosures

c: St. Louis Regional Office
PAMS File: 2015-09-029
Permit Number: