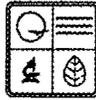


PERMIT BOOK

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: **092014-001**

Project Number: 2014-02-027
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

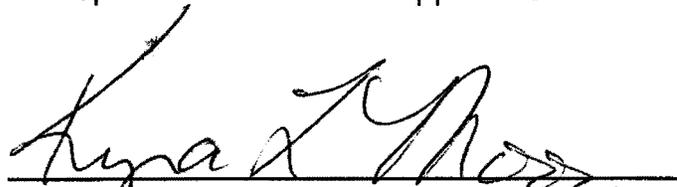
Location Information: City of St. Louis

Application for Authority to Construct was made for:
Installation of an electric Conical Dryer, EP-2913. 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.

SEP - 2 2014

EFFECTIVE DATE



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 start up 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.

Page No.	3
Permit No.	
Project No.	2014-02-027

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
Mallinckrodt LLC shall exclusively use EP-2913 Conical Dryer to produce the pharmaceuticals in Table 1.

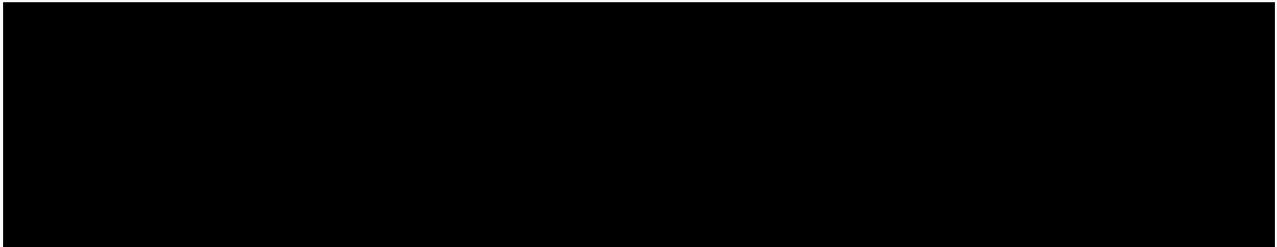
Table 1: Pharmaceuticals which may be dried by EP-2913 Conical Dryer

Code	Product

Page No.	4
Permit No.	
Project No.	2014-02-027

SPECIAL CONDITIONS:

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



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

Project Number: 2014-02-027
Installation ID Number: 510-0017
Permit Number:

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

Complete: March 14, 2014

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

City of St. Louis

REVIEW SUMMARY

- Mallinckrodt LLC has applied for authority to install an electric Conical Dryer, EP-2913.
- HAP emissions are expected from the proposed equipment. EP-2913 Conical Dryer will be subject to MACT GGG which has undergone a Risk and Technology Review (RTR); therefore, this project has no modeling requirements under Missouri's HAP program.
- 40 CFR Part 63, Subpart GGG – *National Emission Standards for Pharmaceuticals Production* is applicable to EP-2913 Conical Dryer. EP-2913 along with other existing equipment will be used to dry pharmaceuticals in a new PMPU at the installation. The installation will be complying with §63.1254(c) which requires the installation to operate a combustion control device (thermal oxidizer) that achieves a maximum outlet TOC concentration of 20 ppmv.
- An existing thermal oxidizer is being used to control the emissions from EP-2913 Conical Dryer 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 VOC are below de minimis levels. A construction permit is required as uncontrolled VOC emissions exceed the VOC insignificant level at 10 CSR 10-6.061(3)(A)3.A.
- 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.
- Emission testing is not required for the equipment by this permit. MACT GGG requires the use of a TOC monitor to ensure that emissions from the existing thermal oxidizer do not exceed the 20 ppmv limitation.
- The installation is required to update their Part 70 Operating Permit application, Project 1997-05-009, to include EP-2913 Conical Dryer 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 and is located 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 2: 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
99-02-012SC	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 Mallinkrodt LLC by the Missouri Air Pollution Control Program.

Table 3: Missouri Air Pollution Control Program Permit History

Permit Number	Description
032007-004	Install a 2.7 MMBtu/hr diesel engine air compressor
072014-004	Installation of a new PMPU

PROJECT DESCRIPTION

Mallinckrodt LLC has applied for the authority to construct an electric Conical Dryer, EP-2913. The new dryer will be used for development, process validation, and initial scaled up of the pharmaceuticals listed in Table 1. The new dryer operates in batches. Each pharmaceutical has a maximum batch size of 50 kg. The length of the drying process for each pharmaceutical has not yet been determined, but plant engineers anticipate one to six hours. To be conservative emission calculations for this project are based on a minimum batch length of one hour. If actual batch length is less than one hour, the installation shall amend this permit to reflect actual operations.

EMISSIONS/CONTROLS EVALUATION

The dryer is electric; therefore, no combustion emissions are expected. Process emissions occur due to the vaporization of solvents. Solvents vary based upon the pharmaceutical being produced. Emissions for each individual HAP, combined HAP, and VOC were based upon the worst-case pharmaceutical for the regulated pollutant and are listed in Table 4.

Table 4: Worst-case emissions

Pollutant	Worst-case Emissions (kg/batch)
VOC	16.7
Combined HAP	8.3
Aniline (62-53-3)	0.05
Methanol (67-56-1)	8.3
MIBK (108-10-1)	1.8
Toluene (108-88-3)	6.5

The new dryer shall comply with §63.1254(c) which requires the operation of a combustion control device (existing thermal oxidizer, 514-CD-10) to achieve a maximum outlet TOC concentration of 20 ppmv. Vapor at a temperature of 140°F enters the thermal oxidizer at a rate of 45,000 scfm. The thermal oxidizer was tested in 2002 and achieved an average TOC destruction efficiency of 99.99 percent, to be conservative 98 percent destruction was used in emissions calculations.

MACT GGG only requires operation of the thermal oxidizer for pharmaceuticals that emit HAP; therefore, worst-case VOC emissions from pharmaceuticals not emitting HAP was also calculated.

No particulate emissions are expected from the new Conical Dryer. Pharmaceuticals leave the dryer using a funnel which is connected to a drum by a plant sheath. The plastic sheath is locked to the funnel and the drum with ring clamps to prevent any product from escaping.

The following table provides an emissions summary for the project. Existing potential emissions from the installation are unknown. Existing actual emissions were taken from the installation's 2013 EIQ. Potential emissions of the application represent the potential of the new equipment, assuming continuous operation (8,760 hours per year).

Table 3: Emissions Summary (tons per year)

Pollutant	Regulatory <i>De Minimis</i> Levels	Existing Potential Emissions	Existing Actual Emissions (2013 EIQ)	Potential Emissions of the Application
PM	25.0	N/D	N/A	N/A
PM ₁₀	15.0	N/D	9.47	N/A
PM _{2.5}	10.0	N/D	9.47	N/A
SO _x	40.0	N/D	0.67	N/A
NO _x	40.0	Major	36.33	N/A
VOC	40.0	N/D	28.66	17.38
CO	100.0	N/D	32.07	N/A
GHG (CO ₂ e)	75,000	N/D	N/A	N/A
HAP	25.0	N/D	7.43	1.60
Methanol (67-56-1)	10.0	N/D	3.33	1.60
Toluene (108-88-3)	10.0	N/D	1.43	1.26
MIBK (108-10-1)	10.0	N/D	0.03	0.35
Aniline (62-53-3)	10.0	N/D	-	0.01

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

Potential VOC emissions from this project are above the insignificance levels of 10 CSR 10-6.061(3)(A)3.A; therefore, a permit was required for the installation of the Conical Dryer, EP-2913.

Potential VOC emissions are below the de minimis level; therefore, modeling was not required.

The Conical Dryer, EP-2913, is subject to 40 CFR Part 63, Subpart GGG which has undergone a Risk and Technology Review; therefore, this project has no modeling requirements under Missouri's HAP program.

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 VOC are below de minimis levels. A construction permit is required as uncontrolled VOC emissions exceed the VOC insignificant level at 10 CSR 10-6.061(3)(A)3.A.

APPLICABLE REQUIREMENTS

Mallinckrodt LLC shall comply with the following applicable requirements applicable to the Conical Dryer, EP-2913. 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 10-6.075 *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 without special conditions.

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

Date

PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated February 13, 2014, received February 14, 2014, designating Mallinckrodt LLC as the owner and operator of the installation.
- U.S. EPA document AP-42, *Compilation of Air Pollutant Emission Factors*, Fifth Edition.

APPENDIX A

Abbreviations and Acronyms

%percent	m/s meters per second
°Fdegrees Fahrenheit	Mgal 1,000 gallons
acfmactual 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
COcarbon monoxide	NSPS New Source Performance Standards
CO₂carbon 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
dscfdry 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
fpsfeet per second	SCC Source Classification Code
ft feet	scfm standard cubic feet per minute
GACT Generally Available Control Technology	SIC Standard Industrial Classification
GHG Greenhouse Gas	SIP State Implementation Plan
gpm gallons per minute	SMAL Screening Model Action Levels
gr grains	SO_x sulfur oxides
GWP Global Warming Potential	SO₂ sulfur dioxide
HAP Hazardous Air Pollutant	tph tons per hour
hr hour	tpy tons per year
hp horsepower	VMT vehicle miles traveled
lbpound	VOC Volatile Organic Compound
lbs/hr pounds per hour	
MACT Maximum Achievable Control Technology	
µg/m³micrograms per cubic meter	

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

RE: New Source Review Permit - Project Number: 2014-02-027

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. 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 submittal of an updated 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: 2014-02-027

Permit Number:

Celebrating 40 years of taking care of Missouri's natural resources.
To learn more about the Missouri Department of Natural Resources visit dnr.mo.gov.