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: 09 2 0 1 4 - 0 0 1  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.
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**
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

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

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

<table>
<thead>
<tr>
<th>Permit Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>032007-004</td>
<td>Install a 2.7 MMBtu/hr diesel engine air compressor</td>
</tr>
<tr>
<td>072014-004</td>
<td>Installation of a new PMPU</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Worst-case Emissions (kg/batch)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VOC</td>
<td>16.7</td>
</tr>
<tr>
<td>Combined HAP</td>
<td>8.3</td>
</tr>
<tr>
<td>Aniline (62-53-3)</td>
<td>0.05</td>
</tr>
<tr>
<td>Methanol (67-56-1)</td>
<td>8.3</td>
</tr>
<tr>
<td>MIBK (108-10-1)</td>
<td>1.8</td>
</tr>
<tr>
<td>Toluene (108-88-3)</td>
<td>6.5</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PM</td>
<td>25.0</td>
<td>N/D</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>PM$_{10}$</td>
<td>15.0</td>
<td>N/D</td>
<td>9.47</td>
<td>N/A</td>
</tr>
<tr>
<td>PM$_{2.5}$</td>
<td>10.0</td>
<td>N/D</td>
<td>9.47</td>
<td>N/A</td>
</tr>
<tr>
<td>SO$_x$</td>
<td>40.0</td>
<td>N/D</td>
<td>0.67</td>
<td>N/A</td>
</tr>
<tr>
<td>NO$_x$</td>
<td>40.0</td>
<td>Major</td>
<td>36.33</td>
<td>N/A</td>
</tr>
<tr>
<td>VOC</td>
<td>40.0</td>
<td>N/D</td>
<td>28.66</td>
<td>17.38</td>
</tr>
<tr>
<td>CO</td>
<td>100.0</td>
<td>N/D</td>
<td>32.07</td>
<td>N/A</td>
</tr>
<tr>
<td>GHG (CO$_2$e)</td>
<td>75,000</td>
<td>N/D</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>HAP</td>
<td>25.0</td>
<td>N/D</td>
<td>7.43</td>
<td>1.60</td>
</tr>
<tr>
<td>Methanol (67-56-1)</td>
<td>10.0</td>
<td>N/D</td>
<td>3.33</td>
<td>1.60</td>
</tr>
<tr>
<td>Toluene (108-88-3)</td>
<td>10.0</td>
<td>N/D</td>
<td>1.43</td>
<td>1.26</td>
</tr>
<tr>
<td>MIBK (108-10-1)</td>
<td>10.0</td>
<td>N/D</td>
<td>0.03</td>
<td>0.35</td>
</tr>
<tr>
<td>Aniline (62-53-3)</td>
<td>10.0</td>
<td>N/D</td>
<td>-</td>
<td>0.01</td>
</tr>
</tbody>
</table>

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
  o 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. 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 February 13, 2014, received February 14, 2014, designating Mallinckrodt LLC as the owner and operator of the installation.

APPENDIX A

Abbreviations and Acronyms

% .......... percent
°F .......... 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
CO₂ .......... carbon dioxide
CO₂e ........ carbon dioxide equivalent
COMS ...... Continuous Opacity Monitor 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
µg/m³ .......... 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
NOₓ .......... nitrogen oxides
NSPS ...... New Source Performance Standards
NSR .......... New Source Review
PM .......... particulate matter
PM₂.₅ ...... particulate matter less than 2.5 microns in aerodynamic diameter
PM₁₀ ...... particulate matter less than 10 microns in aerodynamic diameter
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
SOₓ .......... sulfur oxides
SO₂ .......... sulfur dioxide
tph .......... tons per hour
tpy .......... tons per year
VMT .......... vehicle miles traveled
VOC .......... Volatile Organic Compound
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](http://dnr.mo.gov).