

Missouri Department of dnr.mo.gov

NATURAL RESOURCES

Michael L. Parson, Governor

Carol S. Comer, Director

JAN 07 2019

Ms. Jill Guetersloh
EHS Manager
GlaxoSmithKline Consumer Healthcare Holding (US) LLC
320 South Broadway
St. Louis, MO 63102

RE: New Source Review Permit - Project Number: 2018-11-010

Dear Ms. Guetersloh:

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 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 and your new source review 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.

This permit may include requirements with which you may not be familiar. If you would like the department to meet with you to discuss how to understand and satisfy the requirements contained in this permit, an appointment referred to as a Compliance Assistance Visit (CAV) can be set up with you. To request a CAV, please contact your local regional office or fill out an online request. The regional office contact information can be found at the following website: <http://dnr.mo.gov/regions/>. The online CAV request can be found at <http://dnr.mo.gov/cav/compliance.htm>.

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, United States Post Office Building, 131 West High Street, Third Floor, P.O. Box 1557, Jefferson City, Missouri 65102, phone: 573-751-2422, fax: 573-751-5018, website: www.oa.mo.gov/ahc.



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Ms. Jill Guetersloh
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If you have any questions regarding this permit, please do not hesitate to contact Kathy Kolb, 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



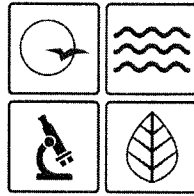
Susan Heckenkamp
New Source Review Unit Chief

SH:kkj

Enclosures

c: St. Louis Regional Office
PAMS File: 2018-11-010

Permit Number: 012019 - 004



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:

012019-004

Project Number: 2018-11-010

Installation Number: 510-1217

Parent Company: GlaxoSmithKline Consumer Healthcare Holding (US) LLC

Parent Company Address: 320 South Broadway, St. Louis, MO 63102

Installation Name: GlaxoSmithKline Consumer Healthcare Holding (US) LLC

Installation Address: 320 South Broadway, St. Louis, MO 63102

Location Information: St. Louis City County, Land Grant 00363

Application for Authority to Construct was made for the installation of a dextrose line at an existing installation. 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.

Director or Designee
Department of Natural Resources

JAN 07 2019

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 Enforcement and Compliance Section of 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 Enforcement and Compliance Section of the Department's Air Pollution Control Program of the anticipated date of start up of this (these) air contaminant source(s). The information must be made available within 30 days of actual startup. Also, you must notify the Department's regional office responsible for the area within which you are located within 15 days after the actual start up of this (these) air contaminant source(s).

A copy of the permit application and this permit and permit review shall be kept at the installation address and shall be made available to Department's 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 source(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 using the contact information below.

Contact Information:

Missouri Department of Natural Resources
Air Pollution Control Program
P.O. Box 176
Jefferson City, MO 65102-0176
(573) 751-4817

The regional office information can be found at the following website:

<http://dnr.mo.gov/regions/>

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 to 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."

GlaxoSmithKline Consumer Healthcare Holding (US) LLC
St. Louis City County, Land Grant 00363

1. Control Device Requirement-Fabric filter
 - A. GlaxoSmithKline Consumer Healthcare Holding (US) LLC shall control emissions from the dextrose line equipment (EP-35 and EP-36) using fabric filters as specified in the permit application.
 - B. The fabric filters shall be equipped with a gauge or meter, which indicates the pressure drop across the control device. These gauges or meters shall be located such that Department of Natural Resources' employees may easily observe them.
 - C. Replacement filters for the fabric filters shall be kept on hand at all times. The bags shall be made of fibers appropriate for operating conditions expected to occur (i.e. temperature limits, acidic and alkali resistance, and abrasion resistance).
 - D. GlaxoSmithKline Consumer Healthcare shall monitor and record the operating pressure drop across the fabric filters at least once every week either manually or recorded electronically in the facility's process control system. They shall also make a visual inspection at least once every 24 hours logging the date/time and observation. If the visual inspection indicates any visible particulate, then a pressure drop reading will be monitored and logged. The operating pressure drop shall be maintained within the design conditions specified by the manufacturer's performance specifications.
 - E. The fabric filters shall be operated and maintained in accordance with the manufacturer's specifications. GlaxoSmithKline Consumer Healthcare Holding (US) LLC shall maintain a copy of the fabric filters manufacturer's operating specifications and performance warranty on site.
 - F. GlaxoSmithKline Consumer Healthcare Holding (US) LLC shall maintain an operating and maintenance log for the fabric filters which shall include the following:
 - 1) Incidents of malfunction, with impact on emissions, duration of event, probable cause, and corrective actions; and

SPECIAL CONDITIONS:

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

- 2) Maintenance activities, with inspection schedule, repair actions, and replacements, etc.
- G. As an alternative to Special Conditions 1.B. and 1.D., visible emissions may be used as an indicator of the proper operation of the control device. During proper operation no visible emissions are expected from this emission unit. The existence of visible emissions will indicate a decrease in the efficiency of the control device and corrective actions will be implemented. Observations will be made using a US EPA Method 22 trained observer and US EPA Method 22 like procedures.
- 1) Frequency: Visible emissions from the exhaust shall be monitored on a daily basis when the process is in operation.
 - 2) Duration: The duration of the observation shall be for a 6 minute time period.
 - 3) Threshold: The condition of no visible emissions is considered normal for this emission unit. When visible emissions are noted from the emission unit, it shall be documented and corrective actions taken.
 - 4) The observation of visible emissions from this emission unit will be considered an excursion and corrective actions shall be implemented within a reasonable period. An excursion does not necessarily indicate a violation of the applicable requirement. When the level of excursions exceed three percent of the of the total number of observations in a six month period and corrective actions fail to return the emission unit to a no visible emission condition, then the permittee shall conduct source testing within 90 days of the last excursion. If the test demonstrates noncompliance with the above emission limitation the permittee shall propose a schedule to implement further corrective actions to bring the source into compliance and demonstrate that compliance.
2. Record Keeping and Reporting Requirements
- A. GlaxoSmithKline Consumer Healthcare Holding (US) 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. These records shall include SDS for all materials used.
 - B. GlaxoSmithKline Consumer Healthcare Holding (US) LLC shall report to the Air Pollution Control Program's Compliance/Enforcement Section, by mail at P.O. Box 176, Jefferson City, MO 65102 or by email at AirComplianceReporting@dnr.mo.gov, no later than 10 days after the end of the month during which any record required by this permit shows an exceedance of a limitation imposed by this permit.

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

Project Number: 2018-11-010
Installation ID Number: 510-1217
Permit Number: 012019-004

Installation Address:

GlaxoSmithKline Consumer Healthcare
Holding (US) LLC
320 South Broadway
St. Louis, MO 63102

Parent Company:

GlaxoSmithKline Consumer Healthcare
Holding (US) LLC
320 South Broadway
St. Louis, MO 63102

St. Louis City County, Land Grant 00363

REVIEW SUMMARY

- GlaxoSmithKline Consumer Healthcare Holding (US) LLC has applied for authority to install a dextrose line.
- The application was deemed complete on November 7, 2018.
- HAP emissions are not expected from the proposed equipment.
- None of the New Source Performance Standards (NSPS) apply to the installation.
- None of the NESHAPs apply to this installation. None of the currently promulgated MACT regulations apply to the proposed equipment.
- A fabric filter is being used to control the PM, PM₁₀ and PM_{2.5} emissions from the equipment in this permit.
- This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of Pollutant are below de minimis levels.
- This installation is located in St. Louis City, a nonattainment area for the 8-hour ozone standard and an attainment/unclassified area for all other criteria pollutants.
- This installation is not on the List of Named Installations found in 10 CSR 10-6.020(3)(B), Table 2. The installation's major source level is 250 tons per year and fugitive emissions are not 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 as a part of this permit. Testing may be required as part of other state, federal or applicable rules.
- An operating permit is not required for this installation because the potential to emit for the installation is de minimis.
- Approval of this permit is recommended with special conditions.

INSTALLATION DESCRIPTION

GlaxoSmithKline’s St. Louis (GSK) facility produces Tums (antacid), OsCal (calcium nutritional supplement) and Citrucel (dietary fiber supplement). Equipment is housed on five floors of the facility which is located on three quarters of a city block in downtown St. Louis.

The following New Source Review permits have been issued to GlaxoSmithKline Consumer Healthcare Holding (US) LLC from the Air Pollution Control Program.

Table 1: Permit History

Permit Number	Description
072015-009	Pharmaceuticals

PROJECT DESCRIPTION

This project includes installation of a dextrose line. Installation of the dextrose line will allow the existing raw material calcium carbonate/dextrose mixture to be replaced with separate calcium carbonate and dextrose raw materials. The dextrose will be received in 2,000 pound “super sacks” at the bulk bag unloader. The dextrose will be pneumatically conveyed through an enclosed vacuum conveyance system to a receiver equipped with a blower. No downstream equipment changes are anticipated. From the receiver, the dextrose will be transferred through an enclosed vacuum conveyance system where it will be combined with calcium carbonate, sugar and/or cornstarch raw materials in existing, permitted equipment to manufacture existing products. This equipment is as described in Permit No. 072015-009.

The dextrose line bulk bag unloader will be equipped with an intake filter. Filters will also be located at the receiver prior to the blower, with a secondary filter prior to the blower itself. A broken bag detector will be located between the dextrose receiver and the blower. Filtered air from the blower is discarded to the clean air system and vents into the building.

As with the existing, permitted equipment and controls, the new dextrose line fabric filters provide a 99.5% control efficiency of particulate, and because product is pneumatically conveyed through enclosed systems, capture efficiency is expected to be 100%. When considering the control efficiency of the fabric filters, facility potential

emissions will remain below de minimis levels after the installation of the dextrose line, as demonstrated by the emissions calculations.

Table 2: Equipment List for this Project

Emission Unit	Equipment Description	MHDR
EP-35	Dextrose Blower	3 tph
EP-36	Dextrose Bulk Bag Unloader	3 tph

EMISSIONS/CONTROLS EVALUATION

The emission factors and control efficiencies used in this analysis were obtained from the EPA on-line database WebFIRE (SCC 3-05-016-15—This emission factor is for product transfer and conveying of lime which has similarities to dextrose. No specific emission factors are available for dextrose. PM₁₀ and PM_{2.5} emissions were considered the same as PM. Particulate emissions are controlled by a fabric filter.

The following table provides an emissions summary for this project. Existing potential emissions were taken from Permit #072015-009. Existing actual emissions were taken from the installation's 2017 EIQ (last full EIQ in 2015). Potential emissions of the application represent the potential of the new equipment, assuming continuous operation (8760 hours per year).

Table 3: Emissions Summary (tpy)

Pollutant	Regulatory De Minimis Levels	Existing Potential Emissions	Existing Actual Emissions (2017 EIQ)	Potential Emissions of the Project	New Installation Potential Emissions
PM	25.0	13.49	N/D	0.29	13.78
PM ₁₀	15.0	3.44	2.02	0.29	3.73
PM _{2.5}	10.0	3.44	2.02	0.29	3.73
SO _x	40.0	N/A	N/A	N/A	N/A
NO _x	40.0	N/A	N/A	N/A	N/A
VOC	40.0	2.075	1.05	N/A	2.075
CO	100.0	N/A	N/A	N/A	N/A
GHG (CO ₂ e)	N/A	N/A	N/A	N/A	N/A
GHG (mass)	N/A	N/A	N/A	N/A	N/A
HAPs	10.0/25.0	N/A	N/A	N/A	N/A

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 PM, PM₁₀ and PM_{2.5} are below de minimis levels.

APPLICABLE REQUIREMENTS

GlaxoSmithKline Consumer Healthcare Holding (US) 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

- *Start-Up, Shutdown, and Malfunction Conditions*, 10 CSR 10-6.050
- *Submission of Emission Data, Emission Fees and Process Information*, 10 CSR 10-6.110
 - Per 10 CSR 10-6.110(4)(B)2.B(II) and (4)(B)2.C(II) a full EIQ is required for the first full calendar year the equipment (or modifications) approved by this permit are in operation.
- *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

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 November 7, 2018, received November 7, 2018, designating GlaxoSmithKline Consumer Healthcare Holding (US) LLC as the owner and operator of the installation.

APPENDIX A

Abbreviations and Acronyms

%percent	m/smeters per second
°Fdegrees Fahrenheit	Mgal1,000 gallons
acfm actual cubic feet per minute	MWmegawatt
BACTBest Available Control Technology	MHDRmaximum hourly design rate
BMPsBest Management Practices	MMBtuMillion British thermal units
BtuBritish thermal unit	MMCFmillion cubic feet
CAM Compliance Assurance Monitoring	MSDSMaterial Safety Data Sheet
CAS Chemical Abstracts Service	NAAQSNational Ambient Air Quality Standards
CEMS Continuous Emission Monitor System	NESHAPs National Emissions Standards for Hazardous Air Pollutants
CFR Code of Federal Regulations	NO_xnitrogen oxides
COcarbon monoxide	NSPSNew Source Performance Standards
CO₂carbon dioxide	NSRNew Source Review
CO_{2e}carbon dioxide equivalent	PMparticulate matter
COMS Continuous Opacity Monitoring System	PM_{2.5}particulate matter less than 2.5 microns in aerodynamic diameter
CSRCode of State Regulations	PM₁₀particulate matter less than 10 microns in aerodynamic diameter
dscfdry standard cubic feet	ppmparts per million
EIQ Emission Inventory Questionnaire	PSDPrevention of Significant Deterioration
EPEmission Point	PTEpotential to emit
EPAEnvironmental Protection Agency	RACTReasonable Available Control Technology
EUEmission Unit	RALRisk Assessment Level
fps feet per second	SCCSource Classification Code
ftfeet	scfmstandard cubic feet per minute
GACT Generally Available Control Technology	SDSSafety Data Sheet
GHG Greenhouse Gas	SICStandard Industrial Classification
gpm gallons per minute	SIPState Implementation Plan
gr grains	SMALScreening Model Action Levels
GWP Global Warming Potential	SO_xsulfur oxides
HAP Hazardous Air Pollutant	SO₂sulfur dioxide
hrhour	SSMStartup, Shutdown & Malfunction
hphorsepower	tphtons per hour
lbpound	tpytons per year
lbs/hr pounds per hour	VMTvehicle miles traveled
MACTMaximum Achievable Control Technology	VOCVolatile Organic Compound
µg/m³micrograms per cubic meter	

Potential and Projected 2019 Actual Emissions Dextrose Line

Operating Data

Projected 2019 Dextrose Throughput (lb/yr) = 1,500,000
 Projected 2019 Dextrose Throughput (ton/yr) = 750
 PM10 and PM25 Emission Factor (lb/ton) = 2.2 SCC 3-05-016-15
 Filter Efficiency = 99.5%

Controlled Potential Emissions Summary for Dextrose Line											
MDNR Construction Permit Insignificant Emission Levels*	1.00	2.75	2.75	2.75	6.88	NA	NA	1.00	NA		
MDNR Construction Permit Modification Thresholds*	15.00	40.00	40.00	40.00	100.00	0.60	25.00	10.00	NA	15.0 tpy	10.0 tpy
Emission Unit Description	PM10 (lb/hr)	SOx (lb/hr)	NOx (lb/hr)	VOC (lb/hr)	CO (lb/hr)	Lead (lb/hr)	HAPs (lb/hr)	PM25 (lb/hr)	NH3 (lb/hr)	PM10 (tpy)	PM2.5 (tpy)
Dextrose Bulk Bag Unloader (EP-36)	0.033							0.033		0.1445	0.1445
Dextrose Blower (EP-35)	0.033							0.033		0.1445	0.1445
Total Emissions Dextrose Line	0.033							0.033		0.2891	0.2891 TOTAL PTE
Totals after installation of Dextrose Line	9.002			1.267				9.002			
Totals prior to installation of Dextrose Line	8.713			1.267				8.713			
Increase in Emissions tons per year	0.289			0.000				0.289			

Projected 2019 Actual Emissions Summary for Dextrose Line											
MDNR Construction Permit Insignificant Emission Levels	1.00	2.75	2.75	2.75	6.88	NA	NA	1.00	NA		
Emission Unit Description	PM10 (tpy)	SOx (tpy)	NOx (tpy)	VOC (tpy)	CO (tpy)	Lead (tpy)	HAPs (tpy)	PM25 (tpy)	NH3 (tpy)		
Dextrose Bulk Bag Unloader (EP-36)	4.13E-03							4.13E-03			
Dextrose Blower (EP-35)	4.13E-03							4.13E-03			
TOTALS	8.25E-03							8.25E-03			

*Although the controlled emissions from the Dextrose Line are below permit thresholds, coverage under a de minimis Construction Permit is required to allow control efficiency of the fabric filters to be considered when calculating potential to emit.

Dextrose blower/Dextrose Bulk Bag unloader MHDR tons/hr Emission factor Source Control Efficiency hour rate lb/hr PTE
 3.0 2.2 SCC 3-05-016-15 100% 0.0330 0.1445

Emission factor source Scc 3-05-016-15