

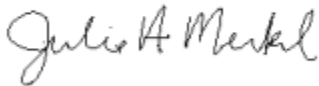
September 29, 2017

Daniel Gossett
Corixa Corporation d/b/a GlaxoSmithKline Vaccines, NA
553 Old Corvallis Road
Hamilton, MT 59840

Dear Mr. Gossett:

Montana Air Quality Permit #4460-03 is deemed final as of September 29, 2017, by the Department of Environmental Quality (Department). This permit is for a pharmaceutical preparations manufacturing plant. All conditions of the Department's Decision remain the same. Enclosed is a copy of your permit with the final date indicated.

For the Department,



Julie A. Merkel
Permitting Services Section Supervisor
Air Quality Bureau
(406) 444-3626



Rhonda Payne
Environmental Science Specialist
Air Quality Bureau
(406) 444-5287

JM:RP
Enclosure

Montana Department of Environmental Quality
Air, Energy & Mining Division

Montana Air Quality Permit #4460-03

Corixa Corporation d/b/a GlaxoSmithKline Vaccines, NA
553 Old Corvallis Road
Hamilton, MT 59840

September 29, 2017



MONTANA AIR QUALITY PERMIT

Issued To: Corixa Corporation d/b/a
GlaxoSmithKline Vaccines,
NA
553 Old Corvallis Road
Hamilton, MT 59840

MAQP: #4460-03
Administrative Amendment (AA) Request
Received: 8/15/2017
Department Decision on AA: 9/13/2017
Permit Final: 9/29/2017

A Montana Air Quality Permit (MAQP), with conditions, is hereby granted to Corixa Corporation, d/b/a, GlaxoSmithKline Vaccines, NA (GSK), pursuant to Sections 75-2-204 and 211 of the Montana Code Annotated (MCA), as amended, and Administrative Rules of Montana (ARM) 17.8.740, *et seq.*, as amended, for the following:

SECTION I: Permitted Facilities

A. Plant Location

GSK's Hamilton Montana Facility is located at 553 Old Corvallis Road in Hamilton, at 46.28567 Latitude, 114.14296 Longitude, and within the S ½ of Section 7, Township 6 North, Range 20 West, Ravalli County, Montana.

B. Current Permit Action

On August 15, 2017, the Department of Environmental Quality – Air Quality Bureau (Department) received a request from GSK to administratively amend MAQP 4460-02 to incorporate recent changes that have occurred at the facility. GSK installed oxidation catalyst units on two of the three diesel-fired emergency generator engines to address odor issues. Additionally, six fume hoods and one bio-hood were removed from the facility. The installation of the oxidation catalysts and the removal of the fume hoods and bio-hood will reduce emissions from the facility; however, a change in allowable emissions was neither requested nor modified in the permit. Additionally, the source no longer conducts any research and development (R&D) onsite, so references to R&D were removed from the permit analysis. The Department made the requested change and updated the permit to reflect current language and rule references used by the Department.

SECTION II: Conditions and Limitations

A. Emission Limitations

1. GSK shall install, operate, and maintain condensation control technology equipment to control emissions from Building 5 and Building 12 pharmaceutical manufacturing operations (ARM 17.8.752).
2. GSK shall operate the condensation emissions control system for Building 5 manufacturing operations such that the maximum 1 hour average cooling water temperature is 17° Celsius (ARM 17.8.752).

3. GSK shall operate the condensation emissions control system for Building 12 manufacturing operations such that the maximum 1 hour average chilled water temperature is 7° Celsius (ARM 17.8.752).
4. GSK may operate up to three diesel engines EGEN1, EGEN2, and EGEN3 to power electric generators named G1, G2, and G3 respectively. The engines shall not exceed 2012 horsepower (hp), 2682 hp, and 671 hp, respectively (ARM 17.8.749).
5. The operation of the three diesel engines/generators shall not exceed 500 hours each per rolling 12-month time period (ARM 17.8.749 and ARM 17.8.752).
6. GSK may operate up to three natural gas fired boilers, Boiler 1, Boiler 2 and Boiler 3; the maximum rated heat input capacity for Boiler 1 and Boiler 2 shall not exceed 16.329 million British thermal units per hour (MMBtu/hr) each and the maximum rated heat input capacity of Boiler 3 shall not exceed 30.659 MMBtu/hr (ARM 17.8.749).
7. GSK shall operate and maintain low oxides of nitrogen (NO_x) burner and flue gas recirculation systems to control NO_x emissions from Boiler 1, Boiler 2 and Boiler 3 (ARM 17.8.752).
8. GSK shall combust only pipeline quality natural gas to control SO₂ emissions from Boiler 1, Boiler 2 and Boiler 3 (ARM 17.8.752).
9. GSK shall use good combustion practices to control CO, PM₁₀, VOC and HAP emissions from Boiler 1, Boiler 2 and Boiler 3 (ARM 17.8.752).
10. GSK shall not cause or authorize emissions to be discharged into the outdoor atmosphere from any sources installed after November 23, 1968, that exhibit an opacity of 20% or greater averaged over 6 consecutive minutes (ARM 17.8.304).
11. GSK shall not cause or authorize the use of any street, road, or parking lot without taking reasonable precautions to control emissions of airborne particulate matter (ARM 17.8.308).
12. GSK shall treat all unpaved portions of the haul roads, access roads, parking lots, or general plant area with water and/or chemical dust suppressant as necessary to maintain compliance with the reasonable precautions limitation in Section II.A.11 (ARM 17.8.749).
13. GSK shall comply with all applicable standards and limitations, and the reporting, recordkeeping and notification requirements contained in 40 CFR 60, Subpart Dc, Standards of Performance for Small Industrial, Commercial, Institutional Steam Generating Units (ARM 17.8.340 and 40 CFR 60, Subpart Dc).

14. GSK shall comply with all applicable standards and limitations, and the reporting, recordkeeping and notification requirements contained at 40 CFR 60, Subpart IIII, Standards of Performance for Stationary Compression Ignition Internal Combustion Engines (ARM 17.8.752, ARM 17.8.340, and 40 CFR 60, Subpart IIII).
15. GSK shall comply with all applicable standards and limitations, and the reporting, recordkeeping, and notification requirements contained in 40 CFR 63, Subpart ZZZZ, National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines, for any applicable diesel engine (ARM 17.8.752, ARM 17.8.342, and 40 CFR 63, Subpart ZZZZ).
16. GSK shall comply with the applicable Management Practices under 40 CFR 63.11495 (a)(1) through 5 as summarized below (ARM 17.8.749).
 - a. GSK process vessels shall be equipped with a cover or lid that must be closed when it is in organic HAP service, except for manual operations that require access, such as material addition and removal, inspection, sampling and cleaning.
 - b. GSK shall practice submerged loading or bottom loading for the transfer of liquids containing chloroform to tanker trucks.
 - c. GSK shall conduct quarterly inspections of process vessels and equipment for each chemical manufacturing process unit in organic HAP service.
 - d. GSK must repair any leak within 15 calendar days after detection of the leak, or document the reason for any delay of repair.
 - e. GSK must keep records of the dates and results of each inspection event, the dates of equipment repairs, and if, applicable, the reasons for any delay in repair.
17. GSK shall comply with the applicable Process Vent Emissions requirements under 40 CFR 63.11496 (ARM 17.8.749).
 - a. GSK must determine the actual uncontrolled organic HAP emissions or estimate emissions from all batch process vents from each chemical manufacturing process unit to demonstrate that they are less than 10,000 lb/yr (ARM 17.8.749).

B. Testing Requirements

1. The Department of Environmental Quality (Department) may require further testing (ARM 17.8.105).
2. All compliance source tests shall conform to the requirements of the Montana Source Test Protocol and Procedures Manual (ARM 17.8.106).

C. Monitoring Requirements

GSK shall install, calibrate, maintain, and operate continuous monitoring and recording equipment on the condensation emission control systems for Building 5 and Building 12 manufacturing operations to measure the chilled/cooling water temperatures. The chilled/cooling water temperatures shall be recorded in hourly averages (ARM 17.8.749).

D. Operational Reporting Requirements

1. GSK shall supply the Department with annual production information for all emission points, as required by the Department in the annual emission inventory request. The request will include, but is not limited to, all sources of emissions identified in the emission inventory contained in the permit analysis.

Production information shall be gathered on a calendar-year basis and submitted to the Department by the date required in the emission inventory request. Information shall be in the units required by the Department. This information may be used to calculate operating fees, based on actual emissions from the facility, and/or to verify compliance with permit limitations (ARM 17.8.505).

2. GSK shall notify the Department of any construction or improvement project conducted, pursuant to ARM 17.8.745, that would include ***the addition of a new emissions unit***, change in control equipment, stack height, stack diameter, stack flow, stack gas temperature, source location, or fuel specifications, or would result in an increase in source capacity above its permitted operation. The notice must be submitted to the Department, in writing, 10 days prior to startup or use of the proposed de minimis change, or as soon as reasonably practicable in the event of an unanticipated circumstance causing the de minimis change, and must include the information requested in ARM 17.8.745(l)(d) (ARM 17.8.745).
3. All records compiled in accordance with this permit must be maintained by GSK as a permanent business record for at least 5 years following the date of the measurement, must be available at the plant site for inspection by the Department, and must be submitted to the Department upon request (ARM 17.8.749).
4. GSK shall document, by month, the hours of operation of each of the three diesel engines/generators. By the 25th day of each month, GSK shall total the hours of operation of the three diesel engines/generators for the previous month. The monthly information will be used to verify compliance with the rolling 12-month limitation in Section II.A.5. The information for each of the previous months shall be submitted along with the annual emission inventory (ARM 17.8.749).

SECTION III: General Conditions

- A. Inspection – GSK shall allow the Department’s representatives access to the source at all reasonable times for the purpose of making inspections or surveys, collecting samples, obtaining data, auditing any monitoring equipment (CEMS, CERMS) or observing any monitoring or testing, and otherwise conducting all necessary functions related to this permit.
- B. Waiver – The permit and the terms, conditions, and matters stated herein shall be deemed accepted if GSK fails to appeal as indicated below.
- C. Compliance with Statutes and Regulations – Nothing in this permit shall be construed as relieving GSK of the responsibility for complying with any applicable federal or Montana statute, rule, or standard, except as specifically provided in ARM 17.8.740, *et seq.* (ARM 17.8.756).
- D. Enforcement – Violations of limitations, conditions and requirements contained herein may constitute grounds for permit revocation, penalties, or other enforcement action as specified in Section 75-2-401, *et seq.*, MCA.
- E. Appeals – Any person or persons jointly or severally adversely affected by the Department’s decision may request, within 15 days after the Department renders its decision, upon affidavit setting forth the grounds therefor, a hearing before the Board of Environmental Review (Board). A hearing shall be held under the provisions of the Montana Administrative Procedures Act. The filing of a request for a hearing does not stay the Department’s decision, unless the Board issues a stay upon receipt of a petition and a finding that a stay is appropriate under Section 75-2-211(11)(b), MCA. The issuance of a stay on a permit by the Board postpones the effective date of the Department’s decision until conclusion of the hearing and issuance of a final decision by the Board. If a stay is not issued by the Board, the Department’s decision on the application is final 16 days after the Department’s decision is made.
- F. Permit Inspection – As required by ARM 17.8.755, Inspection of Permit, a copy of the air quality permit shall be made available for inspection by the Department at the location of the source.
- G. Permit Fee – Pursuant to Section 75-2-220, MCA, failure to pay the annual operation fee by GSK may be grounds for revocation of this permit, as required by that section and rules adopted thereunder by the Board.
- H. Duration of Permit – Construction or installation must begin or contractual obligations entered into that would constitute substantial loss within 3 years of permit issuance and proceed with due diligence until the project is complete or the permit shall expire (ARM 17.8.762).

Montana Air Quality Permit (MAQP) Analysis
Corixa Corporations d/b/a
GlaxoSmithKline Vaccines, NA
MAQP #4460-03

I. Introduction/Process Description

Corixa Corporation, d/b/a, GlaxoSmithKline Vaccines, NA (GSK) owns and operates a pharmaceutical preparations manufacturing plant facility located in Hamilton, Montana. The GSK facility is located at 553 Old Corvallis Road in Hamilton, at 46.28567 Latitude, 114.14296 Longitude, and within the S ½ of Section 7, Township 6 North Range 20 West, Ravalli County, Montana.

The facility consists of two proprietary pharmaceutical manufacturing operations and supporting equipment. The manufacturing operations are called “Building 5 Manufacturing Operations” and “Building 12 Manufacturing Operations” and supporting equipment and emitting units include three boilers, three emergency generators, one fire pump, three fuel storage tanks, two small waste tanks and a 10,000 gallon waste solvent storage tank.

A. Permitted Equipment

The following emitting units are included on the site:

- Boilers: Two 16.329 million British thermal units per hour (MMBtu/hr) and one 30.659 MMBtu/hr Cleaver-Brooks natural gas-fired boilers each equipped with low oxides of nitrogen (NO_x) burners. The boilers satisfy the facility’s process and space-heating needs. The two 16.329 MMBtu/hr boilers were manufactured in 2004 and the 30.659 MMBtu/hr boiler was manufactured in 2006.
- Diesel-powered emergency engines/generators (EGENs), limited to 500 hours per year operation each:
 - G1 – One 2012-horsepower (hp)/2169-brake horsepower (bhp) engine utilizing an oxidation catalyst for odor mitigation, driving a 1500-kiloWatt (kW) generator, manufactured by Caterpillar in 2001
 - G2 – One 2682-hp/2937-bhp engine utilizing an oxidation catalyst for odor mitigation, driving a 2000-kW generator, manufactured by Caterpillar in 2007
 - G3 – One 671-hp/757-bhp engine driving a 500-kW generator, manufactured by Caterpillar in 2007
- One diesel-fired fire pump rated at 110 bhp manufactured in February 2007.
- Four identical Aerco natural gas-fired hot water heaters, each rated at 2 MMBtu/hr.
- One above-ground diesel fuel storage tank (AST) with rated capacity of 6,000 gallons to supply fuel oil to EGENs G1 and G2.

- One AST with a rated capacity of 875 gallons to supply fuel oil to EGEN G3.
- One 180-gallon AST to supply diesel fuel to the fire pump.
- One 10,000-gallon AST for storing waste solvents for offsite disposal located in Building 9.
- One 265-gallon tank to collect waste solvents associated with Building 5 and located in Building 3 (Room 360). The contents of this tank are pumped to the 10,000-gallon tank in Building 9.
- One 265-gallon tank to collect waste solvents associated with Building 12 and located in Building 11 (Room 107). The contents of this tank are pumped to the 10,000 gallon tank in Building 9.
- Approximately 70 laboratory fume hoods of which 34 serve the R&D and Quality Control (QC) operations and 36 serve manufacturing operations.
- Building 5 and Building 12 batch manufacturing operations, which consist of various unit operations, including extraction, purification, and regeneration.

B. Source Description

The facility consists of two proprietary pharmaceutical manufacturing operations and supporting equipment. The GSK site sits on approximately 35 acres and contains various buildings occupying 193,000 square feet of manufacturing, R&D, QC, administration, and utility operations. The manufacturing process operations utilize organic solvents, primarily chloroform and methanol with minor amounts of ethanol and other solvents, in the purification and extraction operations that go on in Building 5 and Building 12.

C. Permit History

On January 28, 2010, GSK was issued **MAQP #4460-00** for the operation of a pharmaceutical preparation manufacturing plant and research and development (R&D) facility and associated equipment.

October 19, 2010, the Department of Environmental Quality – Air Quality Bureau (Department) received a request from GSK for a modification to MAQP #4460-00 to include the following changes. The request was further justified in a letter of additional information received by the Department on December 17, 2010:

- GSK proposed to change the process for producing product in Building 12 from the High Density process to the Low Density process.
- GSK determined that the cooling water temperature supplied to the condensation emission control systems in Building 5 is slightly higher than presented in the original permit application. Also the chilled water temperature supplied to the condensation emission control systems in Building 12 is higher

than presented in the original permit application. These changes in water temperature increase the volatile organic compounds (VOC) and hazardous air pollutants (HAP) emissions from both buildings slightly, and should be noted in the permit.

- GSK proposed to change the method of monitoring the operation of the condensation emission control systems in both Building 5 and Building 12. Instead of measuring the exhaust gas temperature from each condenser, as outlined in Section II.A. of the permit, the inlet cooling water and inlet chilled water temperatures are now measured.
- GSK also noted that there was a misrepresentation of the number of laboratory hoods included as point sources in the emissions inventory in the previous permit. This modification corrected the emissions inventory calculations.

MAQP #4460-01 replaced MAQP #4460-00.

On June 5, 2014, the Department received a request from GSK to incorporate requirements under 40 CFR Part 63, Subpart VVVVVV which GSK must meet as an area source for Chemical Manufacturing Sources. As the pre-control organic Hazardous Air Pollutants (HAPs) are less than the major source threshold values, a Title V operating permit under Subpart VVVVVV is not required. GSK also requested a name change from Corixa Corporation, d/b/a, GlaxoSmithKline Biologicals, NA to Corixa Corporation, d/b/a, GlaxoSmithKline Vaccines, NA. Minor description changes to emission sources were also updated. **MAQP #4460-02** replaced MAQP #4460-01.

D. Current Permit Action

On August 15, 2017, the Department received a request from GSK to administratively amend MAQP 4460-02 to incorporate recent changes that have occurred at the facility. GSK installed oxidation catalyst units on two of the three diesel-fired emergency generator engines to address odor issues. Additionally, six fume hoods and one bio-hood were removed from the facility. The installation of the oxidation catalysts and the removal of the fume hoods and bio-hood will reduce emissions from the facility; however, a change in allowable emissions was neither requested nor modified in the permit. Additionally, the source no longer conducts any research and development (R&D) onsite, so references to R&D were removed from the permit analysis. The Department made the requested change and updated the permit to reflect current language and rule references used by the Department. **MAQP #4460-03** replaces MAQP #4460-02.

E. Additional Information

Additional information, such as applicable rules and regulations, Best Available Control Technology (BACT)/Reasonably Available Control Technology (RACT) determinations, air quality impacts, and environmental assessments, is included in the analysis associated with each change to the permit.

II. Applicable Rules and Regulations

The following are partial explanations of some applicable rules and regulations that apply to the facility. The complete rules are stated in the Administrative Rules of Montana (ARM) and are available, upon request, from the Department. Upon request, the Department will provide references for location of complete copies of all applicable rules and regulations or copies where appropriate.

A. ARM 17.8, Subchapter 1 – General Provisions, including but not limited to:

1. ARM 17.8.101 Definitions. This rule includes a list of applicable definitions used in this chapter, unless indicated otherwise in a specific subchapter.
2. ARM 17.8.105 Testing Requirements. Any person or persons responsible for the emission of any air contaminant into the outdoor atmosphere shall, upon written request of the Department, provide the facilities and necessary equipment (including instruments and sensing devices) and shall conduct tests, emission or ambient, for such periods of time as may be necessary using methods approved by the Department.
3. ARM 17.8.106 Source Testing Protocol. The requirements of this rule apply to any emission source testing conducted by the Department, any source or other entity as required by any rule in this chapter, or any permit or order issued pursuant to this chapter, or the provisions of the Clean Air Act of Montana, 75-2-101, *et seq.*, Montana Code Annotated (MCA).

GSK shall comply with the requirements contained in the Montana Source Test Protocol and Procedures Manual, including, but not limited to, using the proper test methods and supplying the required reports. A copy of the Montana Source Test Protocol and Procedures Manual is available from the Department upon request.

4. ARM 17.8.110 Malfunctions. (2) The Department must be notified promptly by telephone whenever a malfunction occurs that can be expected to create emissions in excess of any applicable emission limitation or to continue for a period greater than 4 hours.
5. ARM 17.8.111 Circumvention. (1) No person shall cause or permit the installation or use of any device or any means that, without resulting in reduction of the total amount of air contaminant emitted, conceals or dilutes an emission of air contaminant that would otherwise violate an air pollution control regulation. (2) No equipment that may produce emissions shall be operated or maintained in such a manner as to create a public nuisance.

B. ARM 17.8, Subchapter 2 – Ambient Air Quality, including, but not limited to the following:

1. ARM 17.8.204 Ambient Air Monitoring
2. ARM 17.8.210 Ambient Air Quality Standards for Sulfur Dioxide
3. ARM 17.8.211 Ambient Air Quality Standards for Nitrogen Dioxide
4. ARM 17.8.212 Ambient Air Quality Standards for Carbon Monoxide

5. ARM 17.8.213 Ambient Air Quality Standard for Ozone
6. ARM 17.8.214 Ambient Air Quality Standard for Hydrogen Sulfide
7. ARM 17.8.220 Ambient Air Quality Standard for Settled Particulate Matter
8. ARM 17.8.221 Ambient Air Quality Standard for Visibility
9. ARM 17.8.222 Ambient Air Quality Standard for Lead
10. ARM 17.8.223 Ambient Air Quality Standard for PM₁₀

GSK must maintain compliance with the applicable ambient air quality standards.

C. ARM 17.8, Subchapter 3 – Emission Standards, including, but not limited to:

1. ARM 17.8.304 Visible Air Contaminants. This rule requires that no person may cause or authorize emissions to be discharged into the outdoor atmosphere from any source installed after November 23, 1968, that exhibit an opacity of 20% or greater averaged over 6 consecutive minutes.
2. ARM 17.8.308 Particulate Matter, Airborne. (1) This rule requires an opacity limitation of less than 20% for all fugitive emission sources and that reasonable precautions be taken to control emissions of airborne particulate matter. (2) Under this rule, GSK shall not cause or authorize the use of any street, road, or parking lot without taking reasonable precautions to control emissions of airborne particulate matter.
3. ARM 17.8.309 Particulate Matter, Fuel Burning Equipment. This rule requires that no person shall cause, allow, or permit to be discharged into the atmosphere particulate matter caused by the combustion of fuel in excess of the amount determined by this rule.
4. ARM 17.8.310 Particulate Matter, Industrial Process. This rule requires that no person shall cause, allow, or permit to be discharged into the atmosphere particulate matter in excess of the amount set forth in this rule.
5. ARM 17.8.322 Sulfur Oxide Emissions--Sulfur in Fuel. This rule requires that no person shall burn liquid, solid, or gaseous fuel in excess of the amount set forth in this rule.
6. ARM 17.8.324 Hydrocarbon Emissions--Petroleum Products. (3) No person shall load or permit the loading of gasoline into any stationary tank with a capacity of 250 gallons or more from any tank truck or trailer, except through a permanent submerged fill pipe, unless such tank is equipped with a vapor loss control device as described in (1) of this rule.
7. ARM 17.8.340 Standard of Performance for New Stationary Sources and Emission Guidelines for Existing Sources. This rule incorporates, by reference, 40 CFR Part 60, Standards of Performance for New Stationary Sources (NSPS). GSK is considered an NSPS-affected facility under 40 CFR Part 60 and is subject to the requirements of the following subparts.
 - a. 40 CFR 60, Subpart A – General Provisions apply to all equipment or facilities subject to an NSPS Subpart as listed below:

- b. 40 CFR 60, Subpart Dc – Standards of Performance for Small Industrial, Commercial, Institutional Steam Generating Units. This subpart applies to industrial, commercial, and institutional boilers with rated heat inputs between 10 and 100 MMBtu/hr that were constructed after June 9, 1989. The water heaters at the GSK facility each have heat input ratings of 2 MMBtu/hr, which is less than 10 MMBtu/hr, so they are exempt from this rule. However, the three boilers were installed in 2004 and 2006, and have rated heat inputs of 16.329 and 30.659 MMBtu/hr. Therefore, the three boilers are subject to the requirements of this standard.
- c. 40 CFR 60, Subparts VV and VVa - Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry. These rules apply to listed equipment types at facilities in the synthetic organic chemical manufacturing industry. GSK is not engaged in the manufacture of synthetic organic chemicals. Therefore, these rules do not apply.
- d. 40 CFR 60, Subpart III - Standards of Performance for Equipment Leaks of VOC Emissions in the Synthetic Organic Chemical Manufacturing Industry Air Oxidation Processes. This rule applies to any facility producing one or more of 36 listed chemicals as a product, co-product, by-product, or intermediate. None of the listed chemicals are produced by GSK; therefore, the rule does not apply.
- e. 40 CFR 60, Subpart NNN - Standards of Performance for Equipment Leaks of VOC Emissions in the Synthetic Organic Chemical Manufacturing Industry Distillation Operations. This rule applies to any facility producing one or more listed chemicals as a product, co-product, by-product, or intermediate. The chemical list includes chloroform and methanol, which are used (but not produced) by GSK as a product, co-product, by-product, or intermediate. Therefore, the rule does not apply.
- f. 40 CFR 60, Subpart RRR - Standards of Performance for Equipment Leaks of VOC Emissions in the Synthetic Organic Chemical Manufacturing Industry Air Oxidation Processes. This rule applies to any facility producing one or more listed chemicals as a product, co-product, by-product, or intermediate. The chemical list includes chloroform and methanol, which are used (but not produced) by GSK as a product, co-product, by-product, or intermediate. In addition, batch reactors are exempt. GSK does not operate any continuous reactor processes. Therefore, this rule does not apply.
- g. 40 CFR 60, Subpart IIII – Standards of Performance for Stationary Compression Ignition Internal Combustion Engines. This standard applies to internal combustion engines with displacement less than 30 liters per cylinder, that are constructed (ordered) after July 11, 2005, and manufactured after April 1, 2006 (except fire pump engines, for which the key date is July 1, 2006). The 2012-hp engine that drives the 1500-kW generator (G1) at the Hamilton facility was installed in 2001, so it is not subject to this rule. However, the 2682-hp and the 671-hp engines

that drive the 2,000-kW and 500-kW generators (G2 and G3, respectively) were installed in 2007 and are therefore subject to this rule. The Fire Pump was manufactured in 2007, and is likewise subject to this rule.

8. ARM 17.8.342 National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Source Categories. The source, as defined and applied in 40 CFR Part 63, shall comply with the requirements of 40 CFR Part 63, as listed below:
 - a. 40 CFR 63, Subpart A – General Provisions apply to all equipment or facilities subject to an NESHAP Subpart as listed below:
 - b. 40 CFR 63, Subpart F – NESHAP for Synthetic Organic Chemical Manufacturing Industry. This rule applies to facilities that are major sources of HAPs that manufacture one or more listed chemicals. The chemical list includes chloroform and methanol, both of which are used (but not manufactured) by GSK. In addition, GSK is not a major source of HAPs; therefore, this rule does not apply to GSK.
 - c. 40 CFR 63, Subpart G – NESHAP for Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater. In accordance with 40 CFR 63.100(b), the applicability provisions of Subpart F also apply to Subparts G and H. Since Subpart F does not apply to GSK, as shown above, Subpart G also does not apply to GSK.
 - d. 40 CFR 63, Subpart H – NESHAP for Synthetic Organic Chemical Manufacturing Industry for Equipment Leaks. In accordance with 40 CFR 63.100(b), the applicability provisions of Subpart F also apply to Subparts G and H. Since Subpart F does not apply to GSK, as shown above, Subpart H also does not apply to GSK.
 - e. 40 CFR 63, Subpart ZZZZ – NESHAPs for Stationary Reciprocating Internal Combustion Engines (RICE). An owner or operator of a stationary reciprocating internal combustion engine (RICE) at a major or area source of HAP emissions is subject to this rule except if the stationary RICE is being tested at a stationary RICE test cell/stand. An area source of HAP emissions is a source that is not a major source. Based on the information submitted by GSK, the RICE equipment used under MAQP #4460-03 are subject to this subpart because GSK is considered an area source of HAPs and GSK operates RICE engines that are considered affected units. Per 40 CFR 63.6590(c), an affected source that meets the requirements in is a new or reconstructed stationary RICE located at an area source must meet the requirements of this part by meeting the NSPS requirements of 40 CFR part 60 subpart IIII, for compression ignition engines or 40 CFR Subpart JJJJ for spark ignition engines.

f. 40 CFR 63, Subpart VVVVVV – NESHAP for Chemical Manufacturing Area Sources. As an area source, the facility is subject to Subpart VVVVVV. However, because GSK has pre-control HAP emissions below the major threshold, GSK is not required to obtain a Title V operating permit. GSK is subject to other requirements incorporated as permit conditions.

D. ARM 17.8, Subchapter 5 – Air Quality Permit Application, Operation, and Open Burning Fees, including, but not limited to:

1. ARM 17.8.504 Air Quality Permit Application Fees. This rule requires that an applicant submit an air quality permit application fee concurrent with the submittal of an air quality permit application. A permit application is incomplete until the proper application fee is paid to the Department. The current permit action is considered an administrative amendment and not subject to an application fee.
2. ARM 17.8.505 Air Quality Operation Fees. An annual air quality operation fee must, as a condition of continued operation, be submitted to the Department by each source of air contaminants holding an air quality permit (excluding an open burning permit) issued by the Department. The air quality operation fee is based on the actual or estimated actual amount of air pollutants emitted during the previous calendar year.

An air quality operation fee is separate and distinct from an air quality permit application fee. The annual assessment and collection of the air quality operation fee, described above, shall take place on a calendar-year basis. The Department may insert into any final permit issued after the effective date of these rules, such conditions as may be necessary to require the payment of an air quality operation fee on a calendar-year basis, including provisions that prorate the required fee amount.

E. ARM 17.8, Subchapter 7 – Permit, Construction, and Operation of Air Contaminant Sources, including, but not limited to:

1. ARM 17.8.740 Definitions. This rule is a list of applicable definitions used in this chapter, unless indicated otherwise in a specific subchapter.
2. ARM 17.8.743 Montana Air Quality Permits--When Required. This rule requires a person to obtain an air quality permit or permit modification to construct, modify, or use any air contaminant sources that have the potential to emit (PTE) greater than 25 tons per year of any pollutant. GSK has a PTE greater than 25 tons per year of NO_x; therefore, an air quality permit is required.
3. ARM 17.8.744 Montana Air Quality Permits--General Exclusions. This rule identifies the activities that are not subject to the Montana Air Quality Permit program.

4. ARM 17.8.745 Montana Air Quality Permits--Exclusion for De Minimis Changes. This rule identifies the de minimis changes at permitted facilities that do not require a permit under the Montana Air Quality Permit Program.
5. ARM 17.8.748 New or Modified Emitting Units--Permit Application Requirements. (1) This rule requires that a permit application be submitted prior to installation, modification, or use of a source. An application is not required for permit actions considered administrative amendments. The current permit action is considered an administrative permit change. (7) This rule requires that the applicant notify the public by means of legal publication in a newspaper of general circulation in the area affected by the application for a permit. An affidavit of publication of public notice was not required for the current permit action because the permit change is considered an administrative permit change.
6. ARM 17.8.749 Conditions for Issuance or Denial of Permit. This rule requires that the permits issued by the Department must authorize the construction and operation of the facility or emitting unit subject to the conditions in the permit and the requirements of this subchapter. This rule also requires that the permit must contain any conditions necessary to assure compliance with the Federal Clean Air Act (FCAA), the Clean Air Act of Montana, and rules adopted under those acts.
7. ARM 17.8.752 Emission Control Requirements. This rule requires a source to install the maximum air pollution control capability that is technically practicable and economically feasible, except that BACT shall be utilized. The required BACT analysis is included in Section III of this permit analysis.
8. ARM 17.8.755 Inspection of Permit. This rule requires that air quality permits shall be made available for inspection by the Department at the location of the source.
9. ARM 17.8.756 Compliance with Other Requirements. This rule states that nothing in the permit shall be construed as relieving GSK of the responsibility for complying with any applicable federal or Montana statute, rule, or standard, except as specifically provided in ARM 17.8.740, *et seq.*
10. ARM 17.8.759 Review of Permit Applications. This rule describes the Department's responsibilities for processing permit applications and making permit decisions on those permit applications that do not require the preparation of an environmental impact statement.
11. ARM 17.8.760 Additional Review of Permit Applications. This rule describes the Department's responsibilities for processing permit applications and making permit decisions on those applications that require an environmental impact statement.

12. ARM 17.8.762 Duration of Permit. An air quality permit shall be valid until revoked or modified, as provided in this subchapter, except that a permit issued prior to construction of a new or modified source may contain a condition providing that the permit will expire unless construction is commenced within the time specified in the permit, which in no event may be less than 1 year after the permit is issued.
 13. ARM 17.8.763 Revocation of Permit. An air quality permit may be revoked upon written request of the permittee, or for violations of any requirement of the Clean Air Act of Montana, rules adopted under the Clean Air Act of Montana, the FCAA, rules adopted under the FCAA, or any applicable requirement contained in the Montana State Implementation Plan (SIP).
 14. ARM 17.8.764 Administrative Amendment to Permit. An air quality permit may be amended for changes in any applicable rules and standards adopted by the Board of Environmental Review (Board) or changed conditions of operation at a source or stack that do not result in an increase of emissions as a result of those changed conditions. The owner or operator of a facility may not increase the facility's emissions beyond permit limits unless the increase meets the criteria in ARM 17.8.745 for a de minimis change not requiring a permit, or unless the owner or operator applies for and receives another permit in accordance with ARM 17.8.748, ARM 17.8.749, ARM 17.8.752, ARM 17.8.755, and ARM 17.8.756, and with all applicable requirements in ARM Title 17, Chapter 8, Subchapters 8, 9, and 10.
 15. ARM 17.8.765 Transfer of Permit. This rule states that an air quality permit may be transferred from one person to another if written notice of intent to transfer, including the names of the transferor and the transferee, is sent to the Department.
- F. ARM 17.8, Subchapter 8 – Prevention of Significant Deterioration of Air Quality, including, but not limited to:
1. ARM 17.8.801 Definitions. This rule is a list of applicable definitions used in this subchapter.
 2. ARM 17.8.818 Review of Major Stationary Sources and Major Modifications-Source Applicability and Exemptions. The requirements contained in ARM 17.8.819 through ARM 17.8.827 shall apply to any major stationary source and any major modification, with respect to each pollutant subject to regulation under the FCAA that it would emit, except as this subchapter would otherwise allow.

This facility is a listed source under the chemical process plant category; however, the GSK facility's PTE is below 100 tons per year of any pollutant. Therefore, the GSK facility is not a major stationary source, and is not currently subject to Prevention of Significant Deterioration (PSD) permitting pursuant to this Subchapter.

G. ARM 17.8, Subchapter 12 – Operating Permit Program Applicability, including, but not limited to:

1. ARM 17.8.1201 Definitions. (23) Major Source under Section 7412 of the FCAA is defined as any source having:
 - a. PTE > 100 tons/year of any pollutant;
 - b. PTE > 10 tons/year of any one hazardous air pollutant (HAP), PTE > 25 tons/year of a combination of all HAPs, or lesser quantity as the Department may establish by rule; or
 - c. PTE > 70 tons/year of particulate matter with an aerodynamic diameter of 10 microns or less (PM₁₀) in a serious PM₁₀ nonattainment area.
2. ARM 17.8.1204 Air Quality Operating Permit Program. (1) Title V of the FCAA amendments of 1990 requires that all sources, as defined in ARM 17.8.1204(1), obtain a Title V Operating Permit. In reviewing and issuing MAQP #4460-03 for GSK, the following conclusions were made:
 - a. The facility's PTE is less than 100 tons/year for any pollutant.
 - b. The facility's PTE is less than 10 tons/year for any one HAP and less than 25 tons/year for all HAPs.
 - c. This source is not located in a serious PM₁₀ nonattainment area.
 - d. This facility is subject to current NSPS (40 CFR 60, Subpart Dc and Subpart IIII).
 - e. This facility is subject to area source provisions of a current NESHAP (40 CFR 63, Subpart ZZZZ and 40 CFR 63, Subpart VVVVVV).
 - f. This source is not a Title IV affected source, or a solid waste combustion unit.
 - g. This source is not an EPA designated Title V source.

Based on these facts, the Department determined that GSK will be a minor source of emissions as defined under Title V. However, if minor sources subject to NSPS are required to obtain a Title V Operating Permit, GSK will be required to obtain a Title V Operating Permit.

III. BACT Determination

A BACT determination is required for each new or modified source. GSK shall install on the new or modified source the maximum air pollution control capability which is technically practicable and economically feasible, except that BACT shall be utilized.

A BACT determination was not required for the current permit action because the permit change is considered an administrative permit change.

IV. Emission Inventory

Emitting Unit	PM	PM ₁₀	PM _{2.5}	NO _x	CO	SO ₂	VOC	HAP
	Tons/Year							
Boiler #1 (16.329 MMBtu/hr)	0.715	0.715	0.715	5.006	2.575	0.122	0.286	0.132
Boiler #2 (16.329 MMBtu/hr)	0.715	0.715	0.715	5.006	2.575	0.122	0.286	0.132
Boiler #3 (32.659 MMBtu/hr)	1.430	1.430	1.430	10.013	5.150	0.243	0.572	0.265
Water Heater a (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
Water Heater b (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
Water Heater c (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
Water Heater d (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
EGEN 1 (1500kW, ~2169bhp) ¹	0.2025	0.2025	0.203	8.15	1.80	0.1875	0.485	0.014
EGEN 2 (2000kW, 2937bhp) ¹	0.0425	0.0425	0.043	8.73	0.475	0.2475	0.1725	0.018
EGEN 3 (500 kW, 757bhp)	0.42	0.42	0.42	5.87	1.26	0.39	0.48	0.005
Firepump (110 bhp)	0.061	0.061	0.061	0.85	0.18	0.056	0.069	0.0007
6,000 gal Diesel Tank							0.00099	0.001
10,030 gal Waste Solvent Tank							0.13	0.121
Fume Hoods ²							0.30	0.30
Manufacturing Process Bldg 5 ³							2.13	2.11
Manufacturing Process Bldg 12 ³							2.75	2.70
Total	3.847	3.847	3.847	47.061	16.899	1.388	7.45	5.86

1. GSK installed oxidation catalysts on these engines to control odors; however, an updated PTE was not submitted as part of the MAQP 4460-03 administrative amendment application because GSK did not intend to receive creditable emissions decreases. Therefore, the permit analysis for MAQP 4460-03 updates the emitting unit description only.
2. Emission factor = 15 lb/yr/hood in accordance with the Research & Development Council of New Jersey guidelines, as submitted by the applicant. (modified 12/2010). MAQP 4460-03 removed 6 of the 76 fume hoods at the plant. Emissions from 30 manufacturing operations fume hoods are accounted for in the Manufacturing Process Buildings emissions. Emissions from the remaining 24 fume hoods are accounted for here. A de minimis action in 2013 added additional fume hoods but did not impact the emission inventory.
3. Emissions provided by applicant, calculated with Emission Master software (modified 12/2010). Note that the emissions inventory table in MAQP#4460-00 did not include itemized VOC and HAP emissions from Bldgs 5 and 12. Based on the information available at the time, these emissions were combined with estimates of emissions from other sources at the site. MAQP#4460-01 includes the emissions from both manufacturing buildings (Bldg. 5 and 12) and has been updated, to represent the current information submitted by the applicant.

The complete emission inventory is on file with the Department.

V. Existing Air Quality

The GSK facility located in Ravalli County near Hamilton, Montana, is classified as attainment/not classified for all pollutants.

VI. Ambient Air Impact Analysis

The Department determined that the impacts from this permitting action will be minor. The Department believes it will not cause or contribute to a violation of any ambient air quality standard.

VII. Taking or Damaging Implication Analysis

As required by 2-10-105, MCA, the Department conducted the following private property taking and damaging assessment.

YES	NO	
X		1. Does the action pertain to land or water management or environmental regulation affecting private real property or water rights?
	X	2. Does the action result in either a permanent or indefinite physical occupation of private property?
	X	3. Does the action deny a fundamental attribute of ownership? (ex.: right to exclude others, disposal of property)
	X	4. Does the action deprive the owner of all economically viable uses of the property?
	X	5. Does the action require a property owner to dedicate a portion of property or to grant an easement? [If no, go to (6)].
		5a. Is there a reasonable, specific connection between the government requirement and legitimate state interests?
		5b. Is the government requirement roughly proportional to the impact of the proposed use of the property?
	X	6. Does the action have a severe impact on the value of the property? (consider economic impact, investment-backed expectations, character of government action)
	X	7. Does the action damage the property by causing some physical disturbance with respect to the property in excess of that sustained by the public generally?
	X	7a. Is the impact of government action direct, peculiar, and significant?
	X	7b. Has government action resulted in the property becoming practically inaccessible, waterlogged or flooded?
	X	7c. Has government action lowered property values by more than 30% and necessitated the physical taking of adjacent property or property across a public way from the property in question?
	X	Takings or damaging implications? (Taking or damaging implications exist if YES is checked in response to question 1 and also to any one or more of the following questions: 2, 3, 4, 6, 7a, 7b, 7c; or if NO is checked in response to questions 5a or 5b; the shaded areas)

Based on this analysis, the Department determined there are no taking or damaging implications associated with this permit action.

VIII. Environmental Assessment

This permitting action will not result in an increase of emissions from the facility and is considered an administrative action; therefore, an environmental assessment is not required.

Analysis Prepared by: Rhonda Payne
Date: August 30, 2017