

DEC 13 2018

Ms. Katie Biri
Regulatory Affairs Manager
Midwest Sterilization Corporation
P.O. Box 411
Jackson, MO 63755

RE: New Source Review Permit - Project Number: 2018-08-071


Dear Ms. Biri:

Enclosed with this letter is your permit to construct. Please study it carefully and refer to Appendix A for a list of common abbreviations and acronyms used in the permit. Also, note the special conditions, if any, on the accompanying pages. The document entitled, "Review of Application for Authority to Construct," is part of the permit and should be kept with this permit in your files. Operation in accordance with these conditions 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.

If you were adversely affected by this permit decision, you may be entitled to pursue an appeal before the administrative hearing commission pursuant to Sections 621.250 and 643.075.6 RSMo. To appeal, you must file a petition with the administrative hearing commission within thirty days after the date this decision was mailed or the date it was delivered, whichever date was earlier. If any such petition is sent by registered mail or certified mail, it will be deemed filed on the date it is mailed; if it is sent by any method other than registered mail or certified mail, it will be deemed filed on the date it is received by the administrative hearing commission, whose contact information is: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102, phone: 573-751-2422, fax: 573-751-5018, website: www.oa.mo.gov/ahc. If you have any questions regarding this permit, please do not hesitate to contact Chia-Wei Young, 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:cyl

Enclosures

c: Southeast Regional Office
PAMS File: 2018-08-071

Permit Number: 122018-0008



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: 122018-008 Project Number: 2018-08-071
Installation Number: 031-0068

Parent Company: Midwest Sterilization Corporation
Parent Company Address: 1204 Lenco Avenue, Jackson, MO 63755
Installation Name: Midwest Sterilization Corporation
Installation Address: 1204 Lenco Avenue, Jackson, MO 63755
Location Information: Cape Girardeau County, S14, T35N, R7E

Application for Authority to Construct was made for:

The installation of a new sterilization chamber. 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

DEC 13 2018

Effective Date

STANDARD CONDITIONS:

Permission to construct may be revoked if you fail to begin construction or modification within two years from the effective date of this permit. Permittee should notify the Air Pollution Control Program if construction or modification is not started within two years after the effective date of this permit, or if construction or modification is suspended for one year or more.

You will be in violation of 10 CSR 10-6.060 if you fail to adhere to the specifications and conditions listed in your application, this permit and the project review. In the event that there is a discrepancy between the permit application and this permit, the conditions of this permit shall take precedence. Specifically, all air contaminant control devices shall be operated and maintained as specified in the application, associated plans and specifications.

You must notify the Department's Air Pollution Control Program of the anticipated date of 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 paragraph (12)(A)10. "Conditions required by permitting authority."

Midwest Sterilization Corporation
Cape Girardeau County, S14, T35N, R7E

1. **Superseding Condition**
The special conditions of this permit supersedes all special conditions found in previously issued construction permits No. 022016-014, 022016-004A, and 122013-007 issued by the Missouri Air Pollution Control Program.
2. **Ethylene Oxide Usage Limitations**
 - A. Midwest Sterilization Corporation shall not use more than 860,049 pounds of ethylene oxide combined in all thirteen (13) of its sterilization chambers in any consecutive 12-month period.
 - B. Attachment A or equivalent forms, such as electronic forms, shall be used to demonstrate compliance with Special Conditions 1.A.
3. **Control Device Requirement – Wet Scrubber**
 - A. Midwest Sterilization Corporation shall control emissions from the vacuum pump vents of all sterilization chambers using a wet scrubber (CD-01) as specified in the permit application.
 - B. The wet scrubber shall be operated and maintained in accordance with the manufacturer's specifications, a copy of which shall be kept on-site.
 - C. The operating pressure drop and the liquid flow rate of the scrubber shall be maintained within the manufacturer's recommended operating conditions (40-120 gpm for liquid flow rate, 10-17 wg for pressure drop).
 - D. Midwest Sterilization Corporation shall install gauges to measure the scrubber pressure drop and the liquid flow rate. The operating pressure drop and the liquid flow rate shall be recorded once every day while the scrubber is in operation to show compliance with Special Condition 3.C.
 - E. The concentration of glycol in the wet scrubber liquor shall not exceed 49.5% by weight, which was established during the September 15, 2004 stack test. Midwest Sterilization Corporation shall sample the wet

SPECIAL CONDITIONS:

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

scrubber liquor once each week to verify that the concentration of glycol is no greater than 49.5% by weight. Sampling shall be performed using methods approved by the Missouri Air Pollution Control Program.

- F. If the glycol concentration for any sample tested in compliance with Special Condition 3.E., is greater than 49.5% by weight, Midwest Sterilization shall implement corrective actions to return the concentration to less than or equal to 49.5%. If corrective actions fail to return the concentration of less than or equal to 49.5%, Midwest Sterilization Corporation shall submit an application to the Air Pollution Control Program to take into account the new information.
 - G. Midwest Sterilization Corporation shall maintain an operating and maintenance log for the wet scrubber which shall include the following:
 - 1) Incidents of malfunction, with impact on emissions, duration of event, probable cause, and corrective actions; and
 - 2) Maintenance activities, with inspection schedule, repair actions, and replacements, etc.
4. Control Device Requirement – Safe Cell II (CD-02)
- A. Midwest Sterilization Corporation shall control the ethylene oxide emissions from all of the aeration chambers using a Safe Cell II control device.
 - B. The medium (beads) for the Safe Cell II control device shall be made of appropriate materials for operating conditions expected to occur. Replacement beads shall be kept onsite.
 - C. The Safe Cell II control device shall be operated and maintained in accordance with the manufacturer's specifications.
 - D. Midwest Sterilization Corporation shall maintain an operating and maintenance log for the Safe Cell II control device which shall include the following:
 - 1) Incidents of malfunction, with impact on emissions, duration of event, probable cause, and corrective actions; and
 - 2) Maintenance activities, with inspection schedule, repair actions, and replacements, etc.
5. Record Keeping and Reporting Requirements
- A. Midwest Sterilization Corporation shall maintain all records required by this permit for not less than five years and shall make them available

SPECIAL CONDITIONS:

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

immediately to any Missouri Department of Natural Resources' personnel upon request. These records shall include SDS for all materials used.

- B. Midwest Sterilization Corporation shall report to the Air Pollution Control Program's Compliance/Enforcement Section, P.O. Box 176, Jefferson City, MO 65102, no later than 10 days after the end of the month during which any record required by this permit show an exceedance of a limitation imposed by this permit.

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

Project Number: 2018-08-071
Installation ID Number: 031-0068
Permit Number: 122018-008

Installation Address:

Midwest Sterilization Corporation
1204 Lenco Avenue
Jackson, MO 63755

Parent Company:

Midwest Sterilization Corporation
1204 Lenco Avenue
Jackson, MO 63755

Cape Girardeau County, S14, T35N, R7E

REVIEW SUMMARY

- Midwest Sterilization Corporation has applied for authority to install one 1,000 cubic feet sterilization chamber.
- The application was deemed complete on September 20, 2018.
- HAP emissions are expected from the proposed equipment. The HAP of concern from this process is ethylene oxide.
- None of the New Source Performance Standards (NSPS) apply to the installation.
- None of the NESHAPs apply to this installation.
- 40 CFR 63, Subpart O, *Ethylene Oxide Emissions Standards for Sterilization Facilities*, of the MACT applies to the installation.
- A wet scrubber is being used to control the emissions from the vacuum pump vent of the sterilization chambers. A Safe Cell II control device is being used to control emissions from the aeration chambers.
- This review was conducted in accordance with Section (5) of Missouri State Rule 10 CSR 10-6.060, *Construction Permits Required*. Potential emissions of all pollutants are below de minimis levels.
- This installation is located in Cape Girardeau County, an attainment area for all 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. The potential emissions of ethylene oxide, a HAP, is greater than the SMAL of 0.1 tpy. However, the EPA has completed the Risk and Technology Review for sterilization facilities, and ambient air quality modeling is not required.
- Emissions testing is not required for the equipment.
- An operating permit is not required for this installation. Potential emissions of all other pollutants, except PM, are below their respective de minimis levels. PM emissions do not trigger operating permit requirements.
- Approval of this permit is recommended with special conditions.

INSTALLATION DESCRIPTION

Midwest Sterilization Corporation is an existing installation in Jackson, Missouri that sterilizes disposable medical devices, dairy cartons, and spices. The largest portion of the business is sterilization of plastic medical supplies. The sterilization process uses ethylene oxide, which is converted to liquid ethylene glycol after wet scrubbing. The facility currently operates twelve (12) sterilization chambers and 21 aeration rooms. This project will add a thirteenth sterilization chamber.

The sterilization process begins with the loading of palletized, non-sterile products into a designated preconditioning room where they are held under elevated temperature and humidity levels for a prescribed amount of time in preparation for sterilization. After the preconditioning step, the load is transferred using forklifts to a sterilization chamber. While in the chamber, vacuum pumps are used to execute a number of evacuations to reduce the concentration of oxygen inside. Nitrogen, steam, and subsequently, a known amount of ethylene oxide are then introduced into the chamber under a vacuum and circulated in and around the product for a specified period of time. The chamber temperature is maintained at about 125 °F by hot water jackets that wrap the chamber.

After sterilization, vacuum pumps are used to remove the ethylene oxide from the chamber and route it to the wet scrubber emission control system. A number of flush cycles are required during the evacuation process to reduce the ethylene oxide to a level that allows for safe chamber unloading. When the sterilization chamber door is opened for unloading, a vent on the opposite end of the chamber (the back vent) automatically activates an exhaust fan that pulls fresh warehouse air through the chamber during the entire unloading process. The back vent, as allowed by 40 CFR 63, Subpart O, is uncontrolled and exhausts to the atmosphere.

The sterilized product is moved from the chamber to a heated aeration room. During a typical 24-72 hour period of time, the aeration process removes residual ethylene oxide from the product. The aeration room emissions are directed through a Safe Cell II emission control system that consists of a series of DR 490 units filled with dry reactant that reduces the ethylene oxide emissions to levels that comply with the applicable 40 CFR Subpart O requirements. When aeration is complete, the sterilized product is stored in the sterile area of the warehouse before shipping.

The following table lists the specifications for the sterilization chambers current at the installation.

Table 1: Sterilization Chamber Specifications

Chamber Number	Ethylene Oxide Usage (lb/cycle)	Average Cycle Duration (hr)	Chamber Volume (cf)
1-6, 12	70	12	1,000
7, 8	142	20	2,000
9-11	199	16	4,423

The chambers listed in Table 1 are labeled differently than in previous permits. In Permit 022016-014, Chambers No. 12 and 13, were permitted, while in Permit 022016-014B, Chamber No. 14 was added. However, Chambers 12 and 13 were never installed. Since the facility only have 2 years from the issuance of the permit to commence construction and the permit was issued over two years ago (February 25, 2016), the facility can no longer construct these chambers without obtaining another construction permit. Chamber No. 14 was constructed and is now considered Chamber No. 12.

The installation is a minor source for construction permits. The following New Source Review permits have been issued to Midwest Sterilization Corporation from the Air Pollution Control Program.

Table 2: Permit History

Permit Number	Description
0780-006	Permitting sterilization chambers.
0187-003	Changing location.
0389-011	Installation of new sterilization chambers.
0490-002	Installation of new sterilization chambers.
1094-005	Addition of new sterilization chambers.
062000-011	Addition of new sterilization chambers, aeration rooms, and ethylene oxide abatement system.
062003-023	Installation of one sterilization chamber and three aeration rooms.
062003-023A	Removing language.
052004-009	New process configuration for MACT compliance.
052004-009A	Removing and replacing special conditions. Added emissions limit.
052004-009B	Limit ethylene oxide emissions and revise back vent emission limit.
122013-007	Addition of a sterilization chamber.
022016-014	Installation of new sterilization chambers.
022016-014A	Correct wet scrubber special condition wording.
022016-014B	Installation of new sterilization chamber. Considered part of the same project as Permit No. 022016-014 and 022016-014A.

PROJECT DESCRIPTION

The installation proposes to add one 1,000 cf sterilization chamber, which will be designated Chamber 13.

Table 3: Process Information for Chamber 13.

Description	Units	Chamber 12
Average Cycle Duration	Hours	12.0
Average Ethylene Oxide Usage	Lb/cycle	70
Maximum Cycle Per Day	Cycle/Day	2.0
Ethylene Oxide Usage	Lb/year	51,100

Ethylene oxide in the new chambers will be pumped to the same wet scrubber (CD-1) as the other existing chambers. Sterilized products will be sent to the existing aeration rooms that are controlled by the safe cell II ethylene oxide control system (CD-02). No additional aeration rooms will be installed. However, emissions from the aeration rooms may increase due to the material from the new sterilization chamber. Three existing natural-gas fired boilers will be used to supply the hot water that maintains the temperature in the chambers.

The installation listed, in the permit application, an average ethylene oxide usage of 70 pounds per cycle for the 1,000 cf chambers. However, in previous permits, the usage was listed as 54 pounds per cycle. The increase in the ethylene oxide usage is not part of this project as this project did not lead to the increase. Instead, the usage from previous projects have been evaluated at a rate that is too low. To account for this, the installation-wide emissions calculations were updated. The new calculations show that the installation-wide emissions of all pollutant are still under their respective *de minimis* levels. The amount of ethylene oxide permitted to be used for the sterilization chambers have also been updated in Special Condition 2.

EMISSIONS/CONTROLS EVALUATION

Emissions of the project include ethylene oxide emissions from the new sterilization chamber, the ethylene oxide emissions from some of the aeration rooms due to the parts processed in the new sterilization chamber, and the particulate emissions from increased haul road usage.

New Sterilization Chamber (No. 13)

The potential emissions of ethylene oxide from the new chambers include emissions exhausted to the wet scrubber as well as the emissions of the back vent. Emissions from the wet scrubber were calculated from mass balances using the amount of ethylene oxide entering the wet scrubber and applying a 99.0% control efficiency. Performance tests conducted in 2004 shows a wet scrubber efficiency of 99.73%. However, a 99.0% was used for a conservative analysis. The scrubber efficiency of

99.73% was based on only one test and the actual efficiency may deviate somewhat from 99.73%. During the scrubbing process, the ethylene oxide is converted to ethylene glycol. The installation is required to monitor the ethylene glycol concentration to ensure that it is below the value obtained during the test (49.5 wt. %), so that the high efficiency can be maintained.

Emissions from the back vent were calculated using an emission factor of 0.008 pounds of ethylene oxide emitted per pound of ethylene oxide used. This emission factor was set in Permit No. 052004-009B and confirmed through a stack test performed in 2005.

The Aeration Chambers

For the aeration chambers, it is very difficult to determine which chamber will be affected by the addition of the new chamber. It is not known which of the aeration chambers will accept parts from the affected sterilization chambers. Therefore, it was assumed that all of the aeration chambers will be affected.

For existing units, the potential emissions of ethylene oxide increase from a project is typically calculated using the potential emissions minus the Baseline Actual Emission (BAE). The Baseline Actual Emissions are the average annual emissions from any 24 consecutive month period from the past five (5) years. However, BAE were not used for this project. The potential emissions of the project using just the potential emissions from the aeration chambers are already calculated to be below the *de minimis* levels.

The potential emissions of the aeration chambers were calculated using the safety cell exhaust maximum flow rate of 40,000 cfm and an ethylene oxide concentration of 1 ppm. In MACT Subpart O, the aeration room vents are required to have either 99% control or 1 ppm ethylene oxide concentration, whichever is less stringent. According to the installation, the 1 ppm concentration is less stringent.

Haul Roads

PM_{2.5}, PM₁₀, and PM emissions from the haul roads were calculated using emission factors from the equations in AP-42, Chapter 13.2.2, *Unpaved Roads*, (11/2006). It is not known how much of the traffic is due to the new sterilization chamber. Therefore, all of the haul road emissions were considered part of this project.

The following table provides an emissions summary for this project. Existing potential emissions were recalculated for this project, taking into account the new ethylene oxide usage in the 1,000 cf sterilization chambers. Existing actual emissions were taken from the installation's 2017 EIQ. The new installation potential emissions reflect the updated usage of ethylene oxide for the 1,000 cf sterilization chambers as well as the emissions from the new sterilization chamber (no. 13). The ethylene oxide emissions from the existing sterilization chambers were calculated using the same method as the new sterilization chamber (no. 13).

Table 4: Emissions Summary (tons per year)

Pollutant	Regulatory <i>De Minimis</i> Levels	Existing Potential Emissions	Existing Actual Emissions (2017 EIQ)	Potential Emissions of the Application	New Installation Potential Emissions
PM	25.0	2.69	N/D	2.69	2.69
PM ₁₀	15.0	1.12	0.32	1.12	1.12
PM _{2.5}	10.0	0.55	0.15	0.55	0.55
SO _x	40.0	0.39	0.01	N/A	0.39
NO _x	40.0	6.47	1.73	N/A	6.47
VOC	40.0	8.77	2.27	1.64	9.23
CO	100.0	5.43	1.45	N/A	5.43
GHG (CO _{2e})	75,000	7,808.00	N/D	N/A	7,808.00
GHG (mass)	0.0	7,762.17	N/D	N/A	7,762.17
Ethylene Oxide	0.1	8.42	N/D	1.64	8.88
Total HAPs	10.0/25.0	8.54	N/D	1.64	9.00

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 all pollutants are below de minimis levels.

APPLICABLE REQUIREMENTS

Midwest Sterilization Corporation 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. For a complete list of applicable requirements for your installation, please consult your operating permit.

GENERAL REQUIREMENTS

- *Submission of Emission Data, Emission Fees and Process Information*, 10 CSR 10-6.110
- *Restriction of Emission of Odors*, 10 CSR 10-6.165

SPECIFIC REQUIREMENTS

- *MACT Regulations*, 10 CSR 10-6.075
 - *Ethylene Oxide Emissions Standards for Sterilization Facilities*, 40 CFR Part 63, Subpart O

STAFF RECOMMENDATION

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

PERMIT DOCUMENTS

The following documents are incorporated by reference into this permit:

- The Application for Authority to Construct form, dated August 31, 2018 received September 20, 2018 designating Midwest Sterilization Corporation as the owner and operator of the installation.

APPENDIX A

Abbreviations and Acronyms

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