

Facility ID: 0125040598 Issuance type: Final State Permit To Operate

This version of facility specific terms and conditions was converted from a database format to an HTML file during an upgrade of the Ohio EPA, Division of Air Pollution Control's permitting software. Every attempt has been made to convert the terms and conditions to look and substantively conform to the permit issued or being drafted in STARS. However, the format of the terms may vary slightly from the original. In addition, although it is not expected, there is a slight possibility that a term and condition may have been inadvertently "left out" of this reproduction during the conversion process. Therefore, if this version is to be used as a starting point in drafting a new version of a permit, it is imperative that the entire set of terms and conditions be reviewed to ensure they substantively mimic the issued permit. The official version of any permit issued final by Ohio EPA is kept in the Agency's Legal section. The Legal section may be contacted at (614) 644-3037.

In addition to the terms and conditions, hyperlinks have been inserted into the document so you may more readily access the section of the document you wish to review.

Finally, the term language under "Part II" and before "A. Applicable Emissions Limitations..." has been added to aid in document conversion, and was not part of the original issued permit.

[Go to Part II for Emissions Unit P001](#)

[Go to Part II for Emissions Unit P002](#)

THIS IS NOT AN OFFICIAL VERSION OF THE PERMIT. SEE PAGE 1 FOR ADDITIONAL INFORMATION

Facility ID: 0125040598 Emissions Unit ID: P001 Issuance type: Final State Permit To Operate

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Part II - Special Terms and Conditions

This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

1. For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.
 - (a) None.
2. For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.
 - (a) None.

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
Ethylene oxide sterilizer controlled with a catalytic incinerator.	OAC rule 3745-31-05 (PTI No. 01-6711)	Ethylene oxide emissions shall not exceed 1.12 pounds per hour, 2.24 pounds per day, and 0.41 ton per year. Hydrochlorofluorocarbons (HCFC) shall not exceed 10.09 pounds per hour, 20.18 pounds per day, and 3.67 tons per year.

2. Additional Terms and Conditions

- (a) The requirements of OAC rule 3745-21-07(G) do not apply because no liquid organic materials are being used in the sterilization process. Both ethylene oxide and HCFC are gases at standard conditions. For this permit, "exhaust operation" is defined as the process of exhausting sterilant gas from the stack of the ethylene oxide sterilizer. Ethylene oxide and HCFC emissions are emitted during this process. The permittee does operate the catalytic incinerator when the emissions unit is in operation; however, the permittee can comply with the emission limitations specified in Section A.1 without taking any credit for the emission reduction achieved by the catalytic incinerator. Therefore, the permit will not require any additional monitoring, record keeping, or reporting requirements for the catalytic incinerator. This permit is applicable for the use of a sterilant gas that contains 10% ethylene oxide and 90% HCFC. The use of a sterilant gas with a higher ethylene oxide concentration requires the approval of the Ohio EPA, Central District Office.

B. Operational Restrictions

1. This emissions unit and emissions unit P002 shall not exhaust ethylene oxide through the common stack at the same time.
2. There shall be no fugitive emissions of ethylene oxide from this emissions unit.
3. The concentration of ethylene oxide in the sterilant gas employed in this emissions unit shall not exceed 10%.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall maintain daily records of the total number of exhaust operations for this emissions unit.
2. The permittee shall maintain weekly records of the pounds of sterilant gas used, including any supporting analyses and computations, and of any exceedance(s) of the ethylene oxide emission limitation specified in Section A.1.

D. Reporting Requirements

1. The permittee shall submit annual reports by February 15 stating the amount of sterilant gas used.
2. Any exceedance(s) of the ethylene oxide emission limitation shall be reported within 24 hours to the Ohio EPA, Central District Office, Air Pollution Control staff or to the Ohio EPA, Division of Emergency and Remedial Response if Central District Office, Air Pollution Control staff are not available to accept or respond to the report. The report should include the reason(s) why the ethylene oxide emission rate exceeded 1.12 pounds per hour, an estimate of mass emissions during the exceedance, and the information required by OAC rule 3745-15-06(B) for all malfunctions. A written report shall be submitted to the Ohio EPA, Central District Office within 30 days of the exceedance(s).

E. Testing Requirements

1. The Ohio EPA, Central District Office reserves the right to perform an engineering and opacity evaluation. If as a result of this evaluation it is deemed necessary to perform a compliance test, the permit holder shall conduct, or have conducted, performance testing of the subject air contaminant source(s) in accordance with procedures approved by the Agency and shall submit a written report, signed by the source owner or his authorized agent, describing the test procedures followed and the results of the tests. The Director or his representative shall be allowed to witness the tests, examine testing equipment and acquire or cause acquisition and/or submission of data and information necessary to provide adequate assurance that source operation, process operating parameters and other conditions, together with testing procedures, provide a valid representation and proper characterization of the source's emissions and/or control equipment performance.
2. Compliance with the emission limitation(s) in Section A.1 of these terms and conditions shall be determined in accordance with the following method(s):

Emission Limitation:
Ethylene oxide emissions shall not exceed 1.12 pounds per hour.

Applicable Compliance Method:
This emission limitation represents the potential to emit for this emissions unit. 11.21 pounds of sterilant gas are used per batch cycle. The amount of ethylene oxide within the sterilant gas can not exceed 10%. Eventhough the exhaust operation associated with each batch cycle can last up to two hours, it is conservatively assumed that all of the ethylene oxide is released during the first hour of the exhaust operation.

Emission Limitation:
Ethylene oxide emissions shall not exceed 2.24 pounds per day.

Applicable Compliance Method:
Compliance shall be determined by multiplying the maximum hourly ethylene oxide emission rate (1.12 lbs/hr) by the maximum number of exhaust operations allowed per day (2).

Emission Limitation:
Ethylene oxide emissions shall not exceed 0.407 ton per year.

Applicable Compliance Method:
Compliance shall be determined by multiplying the annual amount of sterilant gas used (from the records required pursuant to Section C.2) by 0.10 (the maximum allowable percent of ethylene oxide in the sterilant gas), and dividing by 2,000 pounds per ton.

Emission Limitation:
HCFC emissions shall not exceed 10.09 pounds per hour.

Applicable Compliance Method:
This emission limitation represents the potential to emit for this emissions unit. 11.21 pounds of sterilant gas are used per batch cycle. The amount of HCFC within the sterilant gas is 90%. Eventhough the exhaust operation associated with each batch cycle can last up to two hours, it is conservatively assumed that all of the HCFC is released during the first hour of the exhaust operation.

Emission Limitation:
HCFC emissions shall not exceed 20.18 pounds per day.

Applicable Compliance Method:
Compliance shall be determined by multiplying the maximum hourly HCFC emission rate (10.09 lbs/hr) by the maximum number of exhaust operations allowed per day (2).

Emission Limitation:
HCFC emissions shall not exceed 3.67 tons per year.

Applicable Compliance Method:
Compliance shall be determined by multiplying the annual amount of sterilant gas used (from the records required pursuant to Section C.2) by 0.90 (the percent of HCFC in the sterilant gas), and dividing by 2,000 pounds per ton.

F. Miscellaneous Requirements

1. None

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Facility ID: 0125040598 Emissions Unit ID: P002 Issuance type: Final State Permit To Operate

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Part II - Special Terms and Conditions

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1. For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.
 - (a) None.
2. For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.
 - (a) None.

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operation(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the

applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be employed. Additional applicable emissions limitations and/or control measures (if any) may be specified in narrative form following the table.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
Ethylene oxide sterilizer controlled with a catalytic incinerator.	OAC rule 3745-31-05 (PTI No. 01-6711)	Ethylene oxide emissions shall not exceed 1.12 pounds per hour, 2.24 pounds per day, and 0.41 ton per year. Hydrochlorofluorocarbons (HCFC) shall not exceed 10.09 pounds per hour, 20.18 pounds per day, and 3.67 tons per year.

2. Additional Terms and Conditions

- (a) The requirements of OAC rule 3745-21-07(G) do not apply because no liquid organic materials are being used in the sterilization process. Both ethylene oxide and HCFC are gases at standard conditions. For this permit, "exhaust operation" is defined as the process of exhausting sterilant gas from the stack of the ethylene oxide sterilizer. Ethylene oxide and HCFC emissions are emitted during this process. The permittee does operate the catalytic incinerator when the emissions unit is in operation; however, the permittee can comply with the emission limitations specified in Section A.1 without taking any credit for the emission reduction achieved by the catalytic incinerator. Therefore, the permit will not require any additional monitoring, record keeping, or reporting requirements for the catalytic incinerator. This permit is applicable for the use of a sterilant gas that contains 10% ethylene oxide and 90% HCFC. The use of a sterilant gas with a higher ethylene oxide concentration requires the approval of the Ohio EPA, Central District Office.

B. Operational Restrictions

- 1. This emissions unit and emissions unit P001 shall not exhaust ethylene oxide through the common stack at the same time.
- 2. There shall be no fugitive emissions of ethylene oxide from this emissions unit.
- 3. The concentration of ethylene oxide in the sterilant gas employed in this emissions unit shall not exceed 10%.

C. Monitoring and/or Record Keeping Requirements

- 1. The permittee shall maintain daily records of the total number of exhaust operations for this emissions unit.
- 2. The permittee shall maintain weekly records of the pounds of sterilant gas used, including any supporting analyses and computations, and of any exceedance(s) of the ethylene oxide emission limitation specified in Section A.1.

D. Reporting Requirements

- 1. The permittee shall submit annual reports by February 15 stating the amount of sterilant gas used.
- 2. Any exceedance(s) of the ethylene oxide emission limitation shall be reported within 24 hours to the Ohio EPA, Central District Office, Air Pollution Control staff or to the Ohio EPA, Division of Emergency and Remedial Response if Central District Office, Air Pollution Control staff are not available to accept or respond to the report. The report should include the reason(s) why the ethylene oxide emission rate exceeded 1.12 pounds per hour, an estimate of mass emissions during the exceedance, and the information required by OAC rule 3745-15-06(B) for all malfunctions. A written report shall be submitted to the Ohio EPA, Central District Office within 30 days of the exceedance(s).

E. Testing Requirements

- 1. The Ohio EPA, Central District Office reserves the right to perform an engineering and opacity evaluation. If as a result of this evaluation it is deemed necessary to perform a compliance test, the permit holder shall conduct, or have conducted, performance testing of the subject air contaminant source(s) in accordance with procedures approved by the Agency and shall submit a written report, signed by the source owner or his authorized agent, describing the test procedures followed and the results of the tests. The Director or his representative shall be allowed to witness the tests, examine testing equipment and acquire or cause acquisition and/or submission of data and information necessary to provide adequate assurance that source operation, process operating parameters and other conditions, together with testing procedures, provide a valid representation and proper characterization of the source's emissions and/or control equipment performance.

- 2. Compliance with the emission limitation(s) in Section A.1 of these terms and conditions shall be determined in accordance with the following method(s):
Emission Limitation:
Ethylene oxide emissions shall not exceed 1.12 pounds per hour.

Applicable Compliance Method:

This emission limitation represents the potential to emit for this emissions unit. 11.21 pounds of sterilant gas are used per batch cycle. The amount of ethylene oxide within the sterilant gas can not exceed 10%. Eventhough the exhaust operation associated with each batch cycle can last up to two hours, it is conservatively assumed that all of the ethylene oxide is released during the first hour of the exhaust operation.

Emission Limitation:

Ethylene oxide emissions shall not exceed 2.24 pounds per day.

Applicable Compliance Method:

Compliance shall be determined by multiplying the maximum hourly ethylene oxide emission rate (1.12 lbs/hr) by the maximum number of exhaust operations allowed per day (2).

Emission Limitation:

Ethylene oxide emissions shall not exceed 0.407 ton per year.

Applicable Compliance Method:

Compliance shall be determined by multiplying the annual amount of sterilant gas used (from the records

required pursuant to Section C.2) by 0.10 (the maximum allowable percent of ethylene oxide in the sterilant gas), and dividing by 2,000 pounds per ton.

Emission Limitation:

HCFC emissions shall not exceed 10.09 pounds per hour.

Applicable Compliance Method:

This emission limitation represents the potential to emit for this emissions unit. 11.21 pounds of sterilant gas are used per batch cycle. The amount of HCFC within the sterilant gas is 90%. Even though the exhaust operation associated with each batch cycle can last up to two hours, it is conservatively assumed that all of the HCFC is released during the first hour of the exhaust operation.

Emission Limitation:

HCFC emissions shall not exceed 20.18 pounds per day.

Applicable Compliance Method:

Compliance shall be determined by multiplying the maximum hourly HCFC emission rate (10.09 lbs/hr) by the maximum number of exhaust operations allowed per day (2).

Emission Limitation:

HCFC emissions shall not exceed 3.67 tons per year.

Applicable Compliance Method:

Compliance shall be determined by multiplying the annual amount of sterilant gas used (from the records required pursuant to Section C.2) by 0.90 (the percent of HCFC in the sterilant gas), and dividing by 2,000 pounds per ton.

F. Miscellaneous Requirements

1. None