

Facility ID: 0857171794 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 P014](#)
- [Go to Part II for Emissions Unit P015](#)
- [Go to Part II for Emissions Unit P017](#)
- [Go to Part II for Emissions Unit P018](#)

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Facility ID: 0857171794 Emissions Unit ID: P014 Issuance type: Final State Permit To Operate

[Go to the top of this document](#)

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>
P014 - a pan coater for pharmaceuticals, controlled by a catalytic oxidizer	OAC rule 3745-31-05(A)(3) PTI 08-04386	The organic compound (OC) emissions from this emissions unit shall not exceed 0.66 pounds per hour (lb/hr) and 15.84 pounds per day(lbs/day). The requirements of this rule also include compliance with the requirements of OAC rule 3745-35-07(B). See Section A.2.a. below.
	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V)	The OC emissions from this emissions unit shall not exceed 2.89 tons per year (TPY), as a rolling, 365-day summation
	OAC rule 3745-21-07(G)(2)	See Section A.2.a. below. The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. **Additional Terms and Conditions**
 - (a) The OC emissions from this emissions unit shall be controlled through the application of a catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [This catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017, and P019].

B. Operational Restrictions

1. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
2. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information each day:

- a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
- b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information each day:
- The number of batches.
 - The number of gallons of each organic compound solvent material employed in each batch.
 - The density of each organic compound solvent material employed, in pounds per gallon.
 - The pounds of organic compound solvent material employed in each batch, i.e., (b) X (c).
 - The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - The total number of hours the unit was in operation.
 - The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
 - The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.
3. The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and recording equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.
- The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in Section E.2 of this permit.

D. Reporting Requirements

- The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that include the following information:
 - An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0.66 lb/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - An identification of each day during which the controlled organic compound emissions rate exceeded 15.84 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
 - An identification of each day during which the rolling, 365-day OC emission rate exceeded 2.89 tons, and the actual rolling, 365-day OC emission rate for each such day.
- The permittee shall submit quarterly summaries which include a log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
- The permittee shall submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.
- The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the Megtec catalytic oxidizer system required in Section E.2 of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

E. Testing Requirements

- Compliance with the emission limitation(s) in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:

Emission Limitation-
0.66 lb/hr OC

Applicable Compliance Method-
Compliance shall be determined by performance testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.

Emission Limitation-
15.84 lbs/day OC

Applicable Compliance Method-

Compliance shall be determined by performance testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.

Emission Limitation-

2.89 TPY OC, based on a rolling, 365-day summation

Applicable Compliance Method-

Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit and shall be the summation of the daily controlled organic emissions for the calendar year, divided by 2000 lbs/ton.

2. The permittee shall conduct, or have conducted, an annual catalyst activity test on the Megtec catalytic oxidizer system in accordance with the "Megtec Catalyst Sampling and Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.
3. The permittee shall conduct, or have conducted, emission testing on the Megtec catalytic oxidizer in accordance with the following requirements:

- a. The emissions testing shall be conducted within 6 months of permit expiration.
- b. The emissions testing shall be conducted to demonstrate compliance with the allowable mass emission rate and overall control efficiency of 98% for organic compounds.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s): Method 18 of 40 CFR Part 60, Appendix A and Method 25 or 25A of 40 CFR Part 60, Appendix A, as appropriate, before and after the catalytic oxidizer, to demonstrate compliance with the destruction efficiency for organic compounds. The capture efficiency shall be assumed to be 100%, since the unit is totally enclosed with no natural draft openings, and all emissions are vented to the catalytic oxidizer. And if formulation data is not available and/or if required by the regulating agency, Method 24 or 24A of 40 CFR Part 60, Appendix A shall be conducted for the OC content of the solvent materials applied. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

d. The tests shall be conducted while this emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency.

Not later than 30 days prior to the proposed test date(s), this facility shall submit an "Intent to Test" notification. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the tests, and the person(s) who will be conducting the tests. Failure to submit such notification for review and approval prior to the tests may result in the Ohio EPA District Office's or Local Air Agency's refusal to accept the results of the emission tests.

Personnel from the appropriate Ohio EPA District Office or Local Air Agency shall be permitted to witness the tests, examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions tests shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

F. Miscellaneous Requirements

1. The following terms and conditions are federally enforceable: A.1 (only the requirements associated with OAC 3745-35-07(B)), A.2.a., B.1. and 2., C.1 thru 3., D.1.c. and d., D.2. and 3., E.1.c., E.2., and E.3.
2. The monitoring, record keeping and reporting requirements of this permit supercede the monitoring, record keeping and reporting requirements of PTI 08-04386, issued August 27, 2002.

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Facility ID: 0857171794 Emissions Unit ID: P015 Issuance type: Final State Permit To Operate

[Go to the top of this document](#)

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>
P015 -Glatt Fluid Bed Coater for pharmaceuticals, controlled by catalytic oxidizer	OAC rule 3745-31-05(A)(3) PTI 08-04386	The organic compound (OC) emissions from this emissions unit shall not exceed 0.68 pounds per hour (lb/hr) and 16.32 pounds per day (lbs/day). The requirements of this rule also includes compliance with the requirements of OAC rule 3745-35-07(B). See Section A.2.a. below.
	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V)	The OC emissions from this emissions unit shall not exceed 2.99 tons per year (TPY), as a rolling, 365-day summation See Section A.2.a. below.
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. Additional Terms and Conditions

- (a) The OC emissions from this emissions unit shall be controlled through the application of a catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [This catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017, and P019].

B. Operational Restrictions

- 1. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
- 2. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

C. Monitoring and/or Record Keeping Requirements

- 1. The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information each day:

a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

- 2. The permittee shall collect and record the following information each day:

- a. The number of batches.
- b. The number of gallons of each organic compound solvent material employed in each batch.
- c. The density of each organic compound solvent material employed, in pounds per gallon.
- d. The pounds of organic compound solvent material employed in each batch, i.e., (b) X (c).
- e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
- f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
- g. The total number of hours the unit was in operation.
- h. The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
- i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.

- 3. The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the

unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and recording equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in Section E.3 of this permit.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0.68 lb/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emissions rate exceeded 16.32 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - c. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
 - d. An identification of each day during which the rolling, 365-day OC emission rate exceeded 2.99 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include a log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
3. The permittee shall submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the Megtec catalytic oxidizer system required in Section E.3 of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

E. Testing Requirements

1. Compliance with the emission limitation(s) in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:

Emission Limitation-
0.68 lb/hr OC

Applicable Compliance Method-
Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.

Emission Limitation-
16.32 lbs/day OC

Applicable Compliance Method-
Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.

Emission Limitation-
2.99 TPY OC, based on a rolling, 365-day summation

Applicable Compliance Method-
Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit and shall be the summation of the daily controlled organic emissions for the calendar year, divided by 2000 lbs/ton.
2. The permittee shall conduct, or have conducted, an annual catalyst activity test on the Megtec catalytic oxidizer system in accordance with the "Megtec Catalyst Sampling and Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.
3. The permittee shall conduct, or have conducted, emission testing on the Megtec catalytic oxidizer in accordance with the following requirements:
 - a. The emissions testing shall be conducted within 6 months of permit expiration.
 - b. The emissions testing shall be conducted to demonstrate compliance with the allowable mass emission rate and overall control efficiency of 98% for organic compounds.
 - c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s): Method 18 of 40 CFR Part 60, Appendix A and Method 25 or 25A of 40 CFR Part 60, Appendix A, as appropriate, before and after the catalytic oxidizer, to demonstrate compliance with the destruction efficiency for organic compounds. The capture efficiency shall be assumed to be 100%, since the unit is totally enclosed with no natural draft openings, and all emissions are vented to the catalytic oxidizer. And if formulation data is not available and/or if required by the regulating agency, Method 24 or 24A of 40 CFR Part 60, Appendix A shall be conducted for the OC content of the solvent materials applied. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.
 - d. The tests shall be conducted while this emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency. Not later than 30 days prior to the proposed test date(s), this facility shall submit an "Intent to Test" notification. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the

emissions unit operating parameters, the time(s) and date(s) of the tests, and the person(s) who will be conducting the tests. Failure to submit such notification for review and approval prior to the tests may result in the Ohio EPA District Office's or Local Air Agency's refusal to accept the results of the emission tests.

Personnel from the appropriate Ohio EPA District Office or Local Air Agency shall be permitted to witness the tests, examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions tests shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

F. Miscellaneous Requirements

1. The following terms and conditions are federally enforceable: A.1 (only the requirements associated with OAC 3745-35-07(B)), A.2.a., B.1. and 2., C.1. thru 3., D.1.c and d., D.2. thru 4., E.1.c., E.2., and E.3.
2. The monitoring, record keeping and reporting requirements of this permit supercede the monitoring, record keeping and reporting requirements of PTI 08-04386, issued August 27, 2002.

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Facility ID: 0857171794 Emissions Unit ID: P017 Issuance type: Final State Permit To Operate

[Go to the top of this document](#)

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>
P017 - Glatt 120 pharmaceutical spray coater, with catalytic oxidizer	OAC rule 3745-31-05(A)(3) PTI 08-04386	The organic compound (OC) emissions from this emissions unit shall not exceed 5.56 pounds per hour (lbs/hr) and 106.8 pounds per day (lbs/day). The requirements of this rule also include compliance with the requirements of OAC rule 3745-35-07(B). See Section A.2.a. below.
	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V)	The OC emissions from this emissions unit shall not exceed 19.5 tons per year (TPY), as a rolling, 365-day summation See Section A.2.a. below.
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. Additional Terms and Conditions

- (a) The OC emissions from this emissions unit shall be controlled through the application of a catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [This catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017, and P019].

B. Operational Restrictions

1. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in

compliance.

C. Monitoring and/or Record Keeping Requirements

1. The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

The permittee shall collect and record the following information each day:

- a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
 - b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information each day:
 - a. The number of batches.
 - b. The number of gallons of each organic compound solvent material employed in each batch.
 - c. The density of each organic compound solvent material employed, in pounds per gallon.
 - d. The pounds of organic compound solvent material employed in each batch, i.e., (b) X (c).
 - e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - g. The total number of hours the unit was in operation.
 - h. The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
 - i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.
 3. The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and recording equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in Section E.2 of this permit.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with Section A.2. of the General Terms and Conditions of this permit, that include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emission rate exceeded 5.56 lbs/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emission rate exceeded 106.8 lbs/day, and the actual controlled organic compound emission rate for each such day.
 - c. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
 - d. An identification of each day during which the rolling, 365-day OC emission rate exceeded 19.5 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include a log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
3. The permittee shall submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the Megtec catalytic oxidizer system required in Section E.2 of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, catalyst cleaning, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

E. Testing Requirements

1. Compliance with the emissions limitations in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:
Emissions Limitation-
5.56 lbs OC/hr OC

Applicable Compliance Method -
Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and by record keeping as specified in Section C. 2. of this permit.
Emissions Limitation-
106.8 lbs OC/day OC

Applicable Compliance Method-
Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and by record keeping as specified in Section C. 2. of this permit.
Emissions Limitation-
19.5 TPY OC, based on a rolling 365-day summation

Applicable Compliance Method-
Compliance shall be determined based upon record keeping as specified in Section C.2. of this permit.
2. The permittee shall conduct, or have conducted, an annual catalyst activity test on the Megtec catalytic oxidizer system in accordance with the "Megtec Catalyst Sampling and Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.
3. The permittee shall conduct, or have conducted, emission testing on the Megtec catalytic oxidizer in accordance with the following requirements:
 - a. The emissions testing shall be conducted within 6 months of permit expiration.
 - b. The emissions testing shall be conducted to demonstrate compliance with the allowable mass emission rate and overall control efficiency of 98% for organic compounds.
 - c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s): Method 18 of 40 CFR Part 60, Appendix A and Method 25 or 25A of 40 CFR Part 60, Appendix A, as appropriate, before and after the catalytic oxidizer, to demonstrate compliance with the destruction efficiency for organic compounds. The capture efficiency shall be assumed to be 100%, since the unit is totally enclosed with no natural draft openings, and all emissions are vented to the catalytic oxidizer. And if formulation data is not available and/or if required by the regulating agency, Method 24 or 24A of 40 CFR Part 60, Appendix A shall be conducted for the OC content of the solvent materials applied. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.
 - d. The tests shall be conducted while this emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency. Not later than 30 days prior to the proposed test date(s), this facility shall submit an "Intent to Test" notification. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the tests, and the person(s) who will be conducting the tests. Failure to submit such notification for review and approval prior to the tests may result in the Ohio EPA District Office's or Local Air Agency's refusal to accept the results of the emission tests.

Personnel from the appropriate Ohio EPA District Office or Local Air Agency shall be permitted to witness the tests, examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

A comprehensive written report on the results of the emissions tests shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

F. Miscellaneous Requirements

1. The following terms and conditions are federally enforceable: A.1. (only the requirements associated with OAC 3745-35-07(B)), A.2.a., B.1. and 2., C.1. thru 3., D.1.c. and d., E.1.c., E.2., and E.3.
2. The monitoring, record keeping and reporting requirements of this permit supercede the monitoring, record keeping and reporting requirements of PT1 08-04386, issued August 27, 2002.

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

Facility ID: 0857171794 Emissions Unit ID: P018 Issuance type: Final State Permit To Operate

[Go to the top of this document](#)

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>
P018 - Pharmaceutical Drying Oven - GPCG 200	OAC rule 3745-31-05(A)(3) PTI 08-04332	83.2 lbs/day and 15.2 TPY organic compounds (OC)
	OAC rule 3745-21-07(G)(9)(f)	The requirements of this rule also include compliance with the requirements of OAC rule 3745-21-07(G)(9)(f). See Section A.2.a.

2. Additional Terms and Conditions

- (a) Cyclohexane is not a photochemically reactive material, as defined in OAC rule 3745-21-01(C)(5).

B. Operational Restrictions

- 1. None

C. Monitoring and/or Record Keeping Requirements

- 1. The permittee shall maintain the following information each day for this emissions unit:
 - a. The weight of each batch processed, in grams;
 - b. The cyclohexane concentration of each batch before processed, in ppm;
 - c. The total weight of all batches processed, in grams;
 - d. The total cyclohexane concentration for all batches before processed, in ppm;
 - e. The total number of gallons of solvent present for all batches before processed, i.e., [d. X (1 ul/g / 93.6 ppm) X c. X 1 liter/1 X 10⁶ ul X 0.264 gallons/l];
 - f. The cyclohexane OC content, in lbs/gal; and
 - g. The total OC emissions from all batches processed i.e., (e. X f.).

D. Reporting Requirements

- 1. The permittee shall submit annual reports which specify the total OC emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.
- 2. The permittee shall submit deviation reports which identify the days during which solvents other than cyclohexane were employed in this emissions unit. Each report shall identify the cause for the use of the other solvents, and the estimated total quantity of the material emitted during each such day, in pounds. Each report shall be submitted to the Director (the appropriate Ohio EPA District Office or local air agency) within 30 days of the deviation.

E. Testing Requirements

- 1. Compliance with the emission limitations in Section A.1. of this permit shall be determined in accordance with the following methods:
 - Emission Limitation -
83.2 lbs OC/day
 - Applicable Compliance Method -
Compliance shall be based upon the record keeping requirements as specified in Section C.
 - Emission Limitation -
15.2 TPY OC
 - Applicable Compliance Method -
Compliance shall be based upon the record keeping requirements as specified in Section C. and shall be the summation of the daily OC emission rates and divided by 2000 lbs/ton.

F. Miscellaneous Requirements

- 1. none