

Facility ID: 0857171794 Issuance type: Final State Permit To Operate

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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.

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

Facility ID: 0857171794 Emissions Unit ID: P020 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>
P020 - Glatt Fluid Bed Coater GPCG-3 for pharmaceuticals, with catalytic oxidizer	OAC rule 3745-31-05(A)(3) PTI 08-04680	The organic compound (OC) emissions from this emissions unit shall not exceed 0.68 pound per hour. The requirements of this rule also include compliance with the requirements of OAC rules 3745-35-07(B). See Sections A.2.a through A.2.b below.
	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V) OAC rule 3745-31-05(C)	The OC emissions from this emissions unit shall not exceed 2.23 tons per rolling, 12-month period, based upon the summation of the monthly OC emission rates.
	OAC rule 3745-21-07(G)(2) OAC rule 3745-21-07(G)(6)	See Section A.2.a below. The limitations and requirements specified by these rules are less stringent than the requirements established pursuant to OAC rule 3745-31-05(A).

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 Megtec catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017, P019, and P020].
The 0.68 pound per hour OC emission limitation above was established for PTI purposes to reflect the controlled potential to emit for this emissions unit. Therefore, it is not necessary to develop additional monitoring, record keeping and/or reporting requirements to ensure compliance with the emission limitation.

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 a temperature monitor and recorder which measures and records the temperature immediately upstream of the oxidizer's catalyst bed, at least every 15 minutes, when the emissions unit is in operation. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitor and recorder 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; and
- 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 month for this emissions unit:
 - a. the name and identification code of each organic solvent material employed in each batch;
 - b. the number of gallons of each organic solvent material employed in each batch;
 - c. the density of each organic solvent material employed, in pounds per gallon;
 - d. the pounds of all the organic solvent materials employed in each batch, i.e., [summation of (b x c) for organic solvent materials];
 - e. the monthly, before-control OC emission rate for all the organic solvent materials employed, in pounds per month, i.e., the summation of (d) for all batches made during the month;
 - f. the monthly, controlled OC emission rate for all the organic solvent materials employed, in pounds per month, i.e., the value in (e) multiplied by a factor of 1 minus the overall control efficiency from the most recent performance test that demonstrated compliance; and
 - g. the rolling, 12-month summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 11-month period + the current calendar month, divided by 2000 lbs/ton.
 3. The permit to install for this emissions unit (P020) was evaluated based on the actual materials (coatings and solvent materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application, for P020. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Isopropyl Alcohol

TLV (ug/m3): 983,070

Maximum Hourly Emission Rate (lbs/hr): 0.68

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 172.8

MAGLC (ug/m3): 23,410

Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:

 - a. changes in the composition of the materials used (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;
 - b. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
 - c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, then the permittee shall obtain a final permit to install prior to the change.
 4. The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will still satisfy the "Air Toxic Policy:"
 - a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
 - b. documentation of its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
 - c. where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.
 5. 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 the General Terms and Conditions of this permit, that include the following information:
 - a. an identification of all 24-hour averaging periods when the emissions unit was in operation and 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; and
 - b. an identification of each month during which the rolling, 12-month OC emission limitation of 2.23 tons was exceeded, and the actual rolling, 12-month OC emission rate for each such month.
2. The permittee shall submit quarterly summary reports 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. These summary reports shall be submitted by January 31, April 30, July 31 and October 31 of each year and shall cover the previous calendar quarter.
3. 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.

E. Testing Requirements

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

Emission Limitation-
The OC emissions from this emissions unit shall not exceed 0.68 pound per hour.

Applicable Compliance Method-
Compliance with the hourly allowable OC emission limitation above shall be determined based on the results of emission testing conducted in accordance with Method 18, 25, or 25A, as appropriate, of 40 CFR Part 60, Appendix A.

Emission Limitation-
The organic compound (OC) emissions from this emissions unit shall not exceed 2.23 tons per rolling, 12-months

Applicable Compliance Method-
Compliance shall be determined by the record keeping as specified in Section C.2 of this permit.
3. 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 Catalyst Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.
4. The permittee shall conduct, or have conducted, emissions testing on this emissions unit in accordance with the following requirements:
 - a. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rate of 0.68 lb/hr OC and with the overall control efficiency requirement of 98%, by weight, for OC (Performance testing was performed on the Megtec catalytic oxidizer on 9/8/2004 and demonstrated a 99.7% OC destruction efficiency.). Future emission testing for OC shall be conducted at the frequency specified in Ohio EPA engineering Guide #16 based on the results of the initial emission testing.
 - b. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate: 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.
 - c. The tests shall be conducted while this emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the RAPCA
Personnel from the RAPCA 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 RAPCA 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 RAPCA.

F. Miscellaneous Requirements

1. None