

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: P013 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>
P013 - Bead Preparation and coating of pharmaceuticals (granulator, 2-extruders, 2-spheronizers and 4-drying ovens); with catalytic oxidizer and permanent total enclosure (PTE)	OAC rule 3745-31-05(A)(3) PTI 08-04578	The organic compound (OC) emissions from this emissions unit shall not exceed 0.15 pound per hour (lb/hr).  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.c below.
	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V)	The organic compound (OC) emissions from this emissions unit shall not exceed 0.47 tons per year (TPY), as a rolling, 12-month summation.
	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 either the Megtec catalytic oxidizer system or the CSM catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [The Megtec Catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017 and P019. The CSM catalytic oxidizer system is a common OC control device for emissions units P012 and P013.]  
The PTE serving this emissions unit shall be maintained in such a manner as to meet the criteria established for a PTE in Method 204 (40 CFR Part 51, Appendix M) whenever the emissions unit is in operation.  
The 0.15 lb/hr of OC emission limitation from the process was established for PTI purposes to reflect the controlled hourly potential to emit for this emissions unit. Therefore, it is not necessary to develop daily record keeping and/or reporting requirements to ensure compliance with the average hourly limit.

**B. Operational Restrictions**

1. When emissions unit P013 is venting to the CSM catalytic oxidizer the following shall apply:
  - a. 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. [The most recent performance test that demonstrated the emissions unit was in compliance was conducted on May 31, 2001 and June 11, 2001. The test results showed an average inlet temperature of 600 degrees Fahrenheit.]
  - b. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.
2. When emissions unit P013 is venting to the Megtec catalytic oxidizer the following shall apply:
  - a. 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.

b. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

3. Emissions unit P013 shall be equipped with a permanent total enclosure (PTE)\* that shall be installed and operated in accordance with 40 CFR, Part 51, Appendix M, Method 204. The PTE shall meet the following criteria:

a. Any "Natural Draft Opening" (NDO)\* shall be at least 4 equivalent diameters from each VOC emission point.

b. The total area of all NDOs shall not exceed 5 percent of the surface area of the enclosure's four walls, floor and ceiling.

c. The average facial velocity (FV) of air through all NDOs shall be at least 3,600 m/hr (200 fpm) which corresponds to a pressure differential of 0.007 inch of water (the direction of air through all NDOs shall be into the enclosure).

d. All access doors and windows whose areas are not included in paragraph (b) and are not included in the calculation in paragraph (c) shall be closed during routine operation of the process.

e. All VOC emissions must be captured and contained for discharge through a control device.

By satisfying the criteria above for establishing a permanent total enclosure, the total VOC capture efficiency shall be assumed to be 100%.

\* Definitions for PTE and NDO:

Permanent Total Enclosure (PTE) - a permanently installed enclosure that completely surrounds a source of emissions such that all VOC emissions are captured and contained for discharge through a control device.

Natural Draft Opening (NDO) - any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct to which a fan is installed.

4. The permittee performed a demonstration of compliance with Method 204 for this emissions unit, P013, on June 11, 2001, to show that the PTE could not be compromised under normal operating conditions. Therefore, unless otherwise determined by the Ohio EPA, it shall be assumed that the PTE for P013 captures 100% of the VOC emissions from the process when the access doors are closed. Except in the case of an emergency, all access doors to the PTE shall remain closed during process operations.

**C. Monitoring and/or Record Keeping Requirements**

1. For each product batch run on this emissions unit, the permittee shall maintain a record of which catalytic oxidizer system the emission unit is vented and the date.

2. When emissions unit P013 is venting to the CSM catalytic oxidizer, 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 during which 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.

3. When emissions unit P013 is venting to the Megtec catalytic oxidizer 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 during which 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.

4. The permittee shall collect and record the following information each month:

a. the total number of batches\*;

- b. the total number of sub-batches per batch;
- c. the company name and/or identification for each organic solvent material employed in each batch;
- d. the number of gallons of each organic solvent material employed in each batch;
- e. the density of each organic solvent material employed, in pounds per gallon;
- f. the pounds of organic solvent material employed in each batch, i.e., (d) x (e);
- g. the monthly before-control OC emission rate for all organic solvent materials employed, in pounds per month, i.e., the summation of (f) for all batches made in P013 during the month;
- h. the monthly controlled OC emission rate for all organic solvent materials employed, in pounds per month, i.e., the value in (g) multiplied by a factor of 1 minus the control efficiency from the most recent performance test that demonstrated compliance, or 98% until the initial testing is conducted; and
- i. the rolling, 12-month summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (h) for the previous 12-month period divided by 2000 lbs/ton.

\* For emissions units P013, product is measured in sub-batches. A batch is comprised of up to 190 sub-batches. Individual sub-batches are mixed, extruded, and spheronized before being placed into one of four drying ovens. The drying cycle for an oven does not begin until 38 sub-batches have filled that oven to capacity. The drying cycle for the ovens is staggered depending on when each oven is filled.

- 5. The permittee shall perform a preventive maintenance inspection of the CSM 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 the preventive maintenance checklist submitted to the Regional Air Pollution Control Agency on April 12, 2002, 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.

- 6. 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.

- 7. The permittee shall maintain a record of the differential pressure measurements for the permanent total enclosure, as was documented during the demonstration of compliance with Method 204 on June 11, 2001, or any future testing of the permanent total enclosure.

#### 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 shall include the following information:

- a. For the CSM catalytic oxidizer system:

An identification of all 24-hour averaging period when the emissions unit was in operation and vented to the CSM catalytic oxidizer system during which the average combustion temperature within the catalytic oxidizer, 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. For the Megtec catalytic oxidizer system:

An identification of all 24-hour averaging period when the emissions unit was in operation and vented to the Megtec catalytic oxidizer system 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.

- 2. The permittee shall submit quarterly summary reports which include a log of the downtime for the capture (collection) system(s), control device(s), and monitoring equipment(s), 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 an annual report that includes the results of the annual catalyst activity test for the CSM catalytic oxidizer system and 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, catalyst cleaning (CSM system only), 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.
- 4. 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.
- 5. The permittee shall submit quarterly deviation reports that identify any period of time in which any access door was left opened during process operations; and/or either control device was bypassed.

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.

**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 organic compound (OC) emissions from this emissions unit shall not exceed 0.15 pound per hour (lb/hr).
  - Applicable Compliance Method -  
Compliance shall be demonstrated by the Engineering Study conducted between October 27, 2003 and January 16, 2004 which established emissions data based on a worst case batch process.
  - Emission Limitation -  
The OC emissions from this emissions unit shall not exceed 0.47 ton per year (TPY).
  - Applicable Compliance Method -  
Compliance shall be determined by the record keeping as specified in Section C.4 of this permit.
2. The permittee shall conduct, or have conducted, an annual catalyst activity test on the CSM catalytic oxidizer system and the Megtec catalytic oxidizer system in accordance with the "CSM Catalyst Sampling and Catalyst Testing" protocol as submitted to the Regional Air Pollution Control Agency on April 12, 2002 and the "Megtec Catalyst Sampling and Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.
3. Emissions unit P013 has demonstrated that it meets the criteria established for a PTE in Method 204. All doors shall remain closed during processing, except for an emergency. If required by the Ohio EPA, Method 204 shall be repeated if the integrity of the permanent total enclosure is in question (i.e.: negative pressure and/or air flow across the natural draft opening(s) into the bead prep room is in question).
4. The permittee shall conduct, or have conducted, emission testing on the CSM catalytic oxidizer in accordance with the following requirements:
  - a. The emissions testing shall be conducted within 18 months of permit issuance.
  - 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.
5. 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.
6. 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: Sections A.1 (only the requirements associated with OAC 3745-35-07(B)), A.2.a and c, B.1 thru 4, C.1 thru 5, D.1 thru 4, E.1.b., E.2, and E.4.