State of Ohio Environmental Protection Agency

Street Address:
Lazarus Gov. Center
122 S. Front Street
Columbus, OH 43215

TELE: (614) 644-3020 **FAX:** (614) 644-2329

Mailing Address:
Lazarus Gov. Center
P.O. Box 1049
Columbus, OH 43216-1049

RE: DRAFT PERMIT TO INSTALL
MONTGOMERY COUNTY
Application No: 08-04135

DATE: 3/29/00

CERTIFIED MAIL

	TOXIC REVIEW
	PSD
	SYNTHETIC MINOR
	CEMS
	MACT
	NSPS
	NESHAPS
	NETTING
	MAJOR NON-ATTAINMENT
	MODELING SUBMITTED
	GASOLINE DISPENSING FACILITY

Eurand America Inc
Dwight Humbert
845 Center Dr
Vandalia, OH 45377-0000

You are hereby notified that the Ohio Environmental Protection Agency has made a draft action recommending that the Director issue a Permit to Install for the air contaminant source(s) [emissions unit(s)] shown on the enclosed draft permit. This draft action is not an authorization to begin construction or modification of your emissions unit(s). The purpose of this draft is to solicit public comments on the proposed installation. A public notice concerning the draft permit will appear in the Ohio EPA Weekly Review and the newspaper in the county where the facility will be located. Public comments will be accepted by the field office within 30 days of the date of publication in the newspaper. Any comments you have on the draft permit should be directed to the appropriate field office within the comment period. A copy of your comments should also be mailed to Robert Hodanbosi, Division of Air Pollution Control, Ohio EPA, P.O. Box 1049, Columbus, OH, 43266-0149.

A Permit to Install may be issued in proposed of final form based on the draft action, any written public comments received within 30 days of the public notice, or record of a public meeting if one is held. You will be notified in writing of a scheduled public meeting. Upon issuance of a final Permit to Install a fee of **$1200** will be due. Please do not submit any payment now.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469. If you have any questions about this draft permit, please contact the field office where you submitted your application, or Mike Ahern, Field Operations & Permit Section at (614) 644-3631.

Very truly yours,

Thomas G. Rigo
Field Operations and Permit Section
Division of Air Pollution Control

CC: USEPA **RAPCA**
KY **IN** **Miami Valley Reg Plan Com**

DRAFT PERMIT TO INSTALL 08-04135

Application Number: 08-04135

APS Premise Number: 0857171794

Permit Fee: **To be entered upon final issuance**

Name of Facility: Eurand America Inc

Person to Contact: Dwight Humbert

Address: 845 Center Dr
Vandalia, OH 45377-0000

Location of proposed air contaminant source(s) [emissions unit(s)]:
845 Center Dr
Vandalia, Ohio

Description of proposed emissions unit(s):
pan coater, glatt fluid bed coater, LEMS capsule sealer.

The above named entity is hereby granted a Permit to Install for the above described emissions unit(s) pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this permit does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the above described emissions unit(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans and specifications, the above described emissions unit(s) of pollutants will be granted the necessary permits to operate (air) or NPDES permits as applicable.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

Part I - GENERAL TERMS AND CONDITIONS

A. State and Federally Enforceable Permit To Install General Terms and Conditions

1. Monitoring and Related Recordkeeping and Reporting Requirements

a. Except as may otherwise be provided in the terms and conditions for a specific emissions unit, the permittee shall maintain records that include the following, where applicable, for any required monitoring under this permit:

i. The date, place (as defined in the permit), and time of sampling or measurements.

ii. The date(s) analyses were performed.

iii. The company or entity that performed the analyses.

iv. The analytical techniques or methods used.

v. The results of such analyses.

vi. The operating conditions existing at the time of sampling or measurement.

b. Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to, all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

c. Except as may otherwise be provided in the terms and conditions for a specific emissions unit, the permittee shall submit required reports in the following manner:

i. Reports of any required monitoring and/or recordkeeping of federally enforceable information shall be submitted to the appropriate Ohio EPA District Office or local air agency.

ii. Quarterly written reports of (i) any deviations from federally enforceable emission limitations, operational restrictions, and control device operating parameter limitations, excluding deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06, that have been detected by the testing, monitoring and recordkeeping requirements specified in this permit, (ii) the probable cause of such deviations, and (iii) any corrective actions or preventive measures taken, shall be made to the appropriate Ohio EPA District Office or local air agency. The written reports shall be submitted quarterly, i.e., by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. See B.11 below if no deviations occurred during the quarter.

iii. Written reports, which identify any deviations from the federally enforceable monitoring, recordkeeping, and reporting requirements contained in this permit shall be submitted to the appropriate Ohio EPA District Office or local air agency every six months, i.e., by January 31 and July 31 of each year for the previous six calendar months. If no deviations occurred during a six-month period, the permittee shall submit a semi-annual report, which states that no deviations occurred during that period.

iv. Each written report shall be signed by a responsible official certifying that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

2. Scheduled Maintenance/Malfunction Reporting

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction, i.e., upset, of any emissions units or any associated air pollution control system(s) shall be reported to the appropriate Ohio EPA District Office or local air agency in accordance with paragraph (B) of OAC rule 3745-15-06. (The definition of an upset condition shall be the same as that used in OAC rule 3745-15-06(B)(1) for a malfunction.) The verbal and written reports shall be submitted pursuant to OAC rule 3745-15-06**.** Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emission unit(s) that is (are) served by such control system(s).

3. Risk Management Plans

If the permittee is required to develop and register a risk management plan pursuant to section 112(r) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq. ("Act"), the permittee shall comply with the requirement to register such a plan.

4. Title IV Provisions

If the permittee is subject to the requirements of 40 CFR Part 72 concerning acid rain, the permittee shall ensure that any affected emissions unit complies with those requirements. Emissions exceeding any allowances that are lawfully held under Title IV of the Act, or any regulations adopted thereunder, are prohibited.

5. Severability Clause

A determination that any term or condition of this permit is invalid shall not invalidate the force or effect of any other term or condition thereof, except to the extent that any other term or condition depends in whole or in part for its operation or implementation upon the term or condition declared invalid.

6. General Requirements

a. The permittee must comply with all terms and conditions of this permit. Any noncompliance with the federally enforceable terms and conditions of this permit constitutes a violation of the Act, and is grounds for enforcement action or for permit revocation, revocation and reissuance, or modification, or for denial of a permit renewal application.

b. It shall not be a defense for the permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the federally enforceable terms and conditions of this permit.

c. This permit may be modified, reopened, revoked, or revoked and reissued, for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or revocation, or of a notification of planned changes or anticipated noncompliance does not stay any term and condition of this permit.

d. This permit does not convey any property rights of any sort, or any exclusive privilege.

e. The permittee shall furnish to the Director of the Ohio EPA, or an authorized representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon request, the permittee shall also furnish to the Director or an authorized representative of the Director, copies of records required to be kept by this permit. For information claimed to be confidential in the submittal to the Director, if the Administrator of the U.S. EPA requests such information, the permittee may furnish such records directly to the Administrator along with a claim of confidentiality.

7. Fees

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable Permit To Install fees within 30 days after the issuance of this Permit To Install.

8. Federal and State Enforceability

Only those terms and conditions designated in this permit as federally enforceable, that are required under the Act, or any of its applicable requirements, including relevant provisions designed to limit the potential to emit of a source, are enforceable by the Administrator of the U.S. EPA, the State, and citizens under the Act. All other terms and conditions of this permit shall not be federally enforceable and shall be enforceable under State law only.

9. Compliance Requirements

a. Any document (including reports) required to be submitted and required by a federally applicable requirement in this permit shall include a certification by a responsible official that, based on information and belief formed after reasonable inquiry, the statements in the document are true, accurate, and complete.

b. Upon presentation of credentials and other documents as may be required by law, the permittee shall allow the Director of the Ohio EPA or an authorized representative of the Director to:

i. At reasonable times, enter upon the permittee's premises where a source is located or the emissions-related activity is conducted, or where records must be kept under the conditions of this permit.

ii. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit, subject to the protection from disclosure to the public of confidential information consistent with ORC section 3704.08.

iii. Inspect at reasonable times any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit.

iv. As authorized by the Act, sample or monitor at reasonable times substances or parameters for the purpose of assuring compliance with the permit and applicable requirements.

c. The permittee shall submit progress reports to the appropriate Ohio EPA District Office or local air agency concerning any schedule of compliance for meeting an applicable requirement. Progress reports shall be submitted semiannually, or more frequently if specified in the applicable requirement or by the Director of the Ohio EPA. Progress reports shall contain the following:

i. Dates for achieving the activities, milestones, or compliance required in any schedule of compliance, and dates when such activities, milestones, or compliance were achieved.

ii. An explanation of why any dates in any schedule of compliance were not or will not be met, and any preventive or corrective measures adopted.

10. Permit To Operate Application

a. If the permittee is required to apply for a Title V permit pursuant to OAC Chapter 3745-77, the permittee shall submit a complete Title V permit application or a complete Title V permit modification application within twelve (12) months after commencing operation of the emissions units covered by this permit. However, if the proposed new or modified source(s) would be prohibited by the terms and conditions of an existing Title V permit, a Title V permit modification must be obtained before the operation of such new or modified source(s) pursuant to OAC rule 3745-77-04(D) and OAC rule 3745-77-08(C)(3)(d).

b. If the permittee is required to apply for permit(s) pursuant to OAC Chapter 3745-35 , the source(s) identified in this Permit To Install is (are) permitted to operate for a period of up to one year from the date the source(s) commenced operation. Permission to operate is

granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within thirty (30) days after commencing operation of the source(s) covered by this permit.

B. State Only Enforceable Permit To Install General Terms and Conditions

1. Compliance Requirements

The emissions unit(s) identified in this Permit to Install shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

2. Reporting Requirements Related to Monitoring and Recordkeeping Requirements

The permittee shall submit required reports in the following manner:

a. Reports of any required monitoring and/or recordkeeping of state-only enforceable information shall be submitted to the appropriate Ohio EPA District Office or local air agency.

b. Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from state-only required emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and recordkeeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the appropriate Ohio EPA District Office or local air agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly, i.e., by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

3. Permit Transfers

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The appropriate Ohio EPA District Office or local air agency must be notified in writing of any transfer of this permit.

4. Air Pollution Nuisance

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

5. Termination of Permit To Install

This permit to install shall terminate within eighteen months of the effective date of the permit to install if the owner or operator has not undertaken a continuing program of installation or modification or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation or modification. This deadline may

be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the party shows good cause for any such extension.

6. Construction of New Sources(s)

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed sources are inadequate or cannot meet applicable standards.

If the construction of the proposed emissions unit(s) has already begun or has been completed prior to the date the Director of the Environmental Protection Agency approves the permit application and plans, the approval does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the approved plans. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of the Permit to Install does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Approval of the plans in any case is not to be construed as an approval of the facility as constructed and/or completed. Moreover, issuance of the Permit to Install is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities prove to be inadequate or cannot meet applicable standards.

7. Public Disclosure

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

8. Applicability

This Permit to Install is applicable only to the emissions unit(s) identified in the Permit To Install. Separate application must be made to the Director for the installation or modification of any other emissions unit(s).

9. Best Available Technology

As specified in OAC Rule 3745-31-05, all new sources must employ Best Available Technology (BAT). Compliance with the terms and conditions of this permit will fulfill this requirement.

10. Construction Compliance Certification

The applicant shall provide Ohio EPA with a written certification (see enclosed form) that the facility has been constructed in accordance with the Permit To Install application and the terms and conditions of the Permit to Install. The certification shall be provided to Ohio EPA upon completion of construction but prior to startup of the source.

11. Additional Reporting Requirements When There Are No Deviations of Federally Enforceable Emission Limitations, Operational Restrictions, or Control Device Operating Parameter Limitations (See Section A of This Permit)

If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly, i.e., by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters.

C. Permit To Install Summary of Allowable Emissions

The following information summarizes the total allowable emissions, by pollutant, based on the individual allowable emissions of each air contaminant source identified in this permit.

SUMMARY (for informational purposes only)
TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

Pollutant	Tons Per Year
organic compounds	**6.06 TPY**

Part II - FACILITY SPECIFIC TERMS AND CONDITIONS

A. State and Federally Enforceable Permit To Install Facility Specific Terms and Conditions

None.

B. State Only Enforceable Permit To Install Facility Specific Terms and Conditions

None.

Part III - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. State and Federally Enforceable Section

I. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(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 specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P014 - a pan coater for pharmaceuticals, controlled by a catalytic incinerator	OAC rule 3745-31-05(A)(3)	0.66 lb/hr as an average over the batch cycle, 15.84 lbs/day, 2.89 TPY organic compounds
	OAC rule 3745-21-07(G)(2)	See A.2.a

2. Additional Terms and Conditions

2.a The emission limitations specified in OAC rule 3745-21-07(G)(2) are less stringent than the emission limitation specified above as Best Available Technology (BAT).

II. Operational Restrictions

1. The organic compound (OC) emissions from emissions unit P014 shall be controlled through the application of a catalytic incinerator. The catalytic incinerator shall operate at a destruction efficiency of at least 98 percent.

2. The average temperature of the exhaust gases immediately before the catalyst bed, for any 3-hour block of time 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 average temperature difference across the catalyst bed, for any 3-hour block of time when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

III. Monitoring and/or Recordkeeping Requirements

1. The permittee shall operate and maintain continuous temperature monitor and recorder(s) which measure and record(s) the temperature immediately upstream and downstream of the incinerator's catalyst bed 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(s) 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 for each day:

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

   b. All 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than than 50 degrees Fahrenheit below the average temperature of the exhaust gases during the most recent performance test that demonstrated the emissions unit was in compliance.

   c. All 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent performance test that demonstrated the emissions unit was in compliance.

2. The permittee shall collect and record the following information each day when the emissions unit is in operation:

   a. the number of batches each day;

   b. the number of gallons of each organic compound solvent material in each batch;

   c. the density of the organic compound solvent material employed in each batch, (pounds/gallon);

   d. the pounds of organic compound solvent material employed in each batch, i.e., (b) X (c);

   e. the before-control organic compound emission rate for all organic compound solvent materials employed, in pounds/day, i.e., (a) X (d);

   f. the controlled organic compound emission rate for all of the organic compound solvent materials employed, each day, by multiplying the amount in (e) 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 organic compound emission rate, i.e., (f/g), in pounds per hour (average).

IV. Reporting Requirements

1. In accordance with paragraph A.2. of the General Terms and Conditions, the permittee shall submit quarterly deviation (excursion) reports to the Director (the appropriate Ohio EPA District Office or local air agency) which include the following information for this emissions unit:

   a. 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.

   b. 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.

   c. an identification of all 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than fifty degrees Fahrenheit below the average combustion temperature of the exhaust gases during the most recent performance test that demonstrated the emissions unit was in compliance.

   d. an identification of all three hour blocks of time (when the emission unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent performance test that demonstrated the emissions unit was in compliance.

   e. 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.

2. 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.

V. Testing Requirements

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

a. Emission Limitation

0.66 lb/hr, as an average over the batch cycle

Applicable Compliance Method

Compliance shall be determined by emission testing as specified in section V.2. and the recordkeeping as specified in III.2.

b. Emission Limitation

15.84 lbs/day OC

Applicable Compliance Method

Compliance shall be determined by performance testing and recordkeeping as specified in III.2.

c. Emission Limitation

2.89 TPY OC

Applicable Compliance Method

Compliance shall be determined by the recordkeeping in III.2. and shall be the summation of the daily controlled organic emissions for the calendar year.

2. Emission Testing Requirements

The permittee shall conduct, or have conducted, emission testing on this emissions unit in accordance with the following requirements:

a. The emissions testing shall be conducted within ninety days after permit issuance.

b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates 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, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

d. The test(s) shall be conducted while the 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.

VI. Miscellaneous Requirements

None.

B. State Only Enforceable Section

I. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(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 specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P014 - a pan coater for pharmaceuticals, controlled by a catalytic incinerator		Compliance with Air Toxics Policy

2. Additional Terms and Conditions

None.

II. Operational Restrictions

None.

III. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that a changed emissions unit will still satisfy the Air Toxic Policy:

   a. a description of the parameters changed (composititon 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.

IV. Reporting Requirements

None.

V. Testing Requirements

None.

VI. Miscellaneous Requirements

Air Toxic Policy Clarifying Language

1. The permit to install for this emissions unit (P014) was evaluated based on the actual materials specified by the permittee in the permit to install application. The emission limitation(s) specified in this permit was (were) established using the Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") and is (are) based on both the materials used and the design parameters of the emissions unit's exhaust system, as specified in the application. The Ohio EPA's "Air Toxic Policy" was applied for each pollutant using the SCREEN 3.0 model and comparing the predicted 1-hour maximum ground-level concentration to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worse case" each pollutant(s):

   Pollutant: Methanol

   TLV (ug/m3): 261,758

   Maximum Hourly Emission Rate (lbs/hr): 0.66

   Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 187.5

   MAGLC (ug/m3): 6232.33

   Physical changes or changes in the method of operation of the emissions unit that result in changes to the factors affecting the air toxic analysis could result in noncompliance with this permit to install. In order to avoid this noncompliance situation, prior to initiating any changes, permittees are required to conduct an evaluation to determine that the "Air Toxic Policy" is still satisfied. Changes that can affect the "Air Toxic Policy" include, but are not limited to, 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.)

The Ohio EPA will not consider any of the above-mentioned as a “modification” requiring a permit to install, if the following conditions are met:

a. the change is not otherwise considered a “modification” under OAC Chapter 3745-31;

b. the permittee can continue to comply with the allowable emission limitations specified in its permit to install; and,

c. prior to the change, the applicant conducts an evaluation pursuant to the Air Toxic Policy, determines that the changed emissions unit still satisfies the Air Toxic Policy, and the permittee maintains documentation that identifies the change and the results of the application of the Air Toxic Policy for the change.

For any change to the emissions unit or its method of operation that either would require an increase in the emission limitation(s) established by this permit or would otherwise be considered a "modification" as defined in OAC rule 3745-31-01, the permittee shall obtain a final permit to install prior to the change.

Part III - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. State and Federally Enforceable Section

I. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(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 specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P015 -Glatt Fluid Bed Coater for pharmaceuticals, controlled by catalytic incinerator	OAC rule 3745-31-05(A)(3)	0.68 lb/hr as an average over the batch cycle, 16.32 lbs/day, 2.99 TPY organic compunds
	OAC rule 3745-21-07(G)(2)	See A.2.a.

2. Additional Terms and Conditions

2.a The emission limitations specified in OAC rule 3745-21-07(G)(2) are less stringent than the emission limitation specified above as Best Available Technology (BAT).

II. Operational Restrictions

1. The organic compound (OC) emissions from emissions unit P015 shall be controlled through the application of a catalytic incinerator. The catalytic incinerator shall operate at a destruction efficiency of at least 98 percent.

2. The average temperature of the exhaust gases immediately before the catalyst bed, for any 3-hour block of time 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 average temperature difference across the catalyst bed, for any 3-hour block of time when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

III. Monitoring and/or Recordkeeping Requirements

1. The permittee shall operate and maintain continuous temperature monitor and recorder(s) which measure and record(s) the temperature immediately upstream and downstream of the incinerator's catalyst bed 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(s) 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 for each day:

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

   b. All 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than than 50 degrees Fahrenheit below the average temperature of the exhaust gases during the most recent performance test that demonstrated the emissions unit was in compliance.

   c. All 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent performance test that demonstrated the emissions unit was in compliance.

2. The permittee shall collect and record the following information each day when the emissions unit is in operation:

   a. the number of batches each day;

   b. the number of gallons of each organic compound solvent material in each batch;

   c. the density of the organic compound solvent material employed in each batch, (pounds/gallon);

   d. the pounds of organic compound solvent material employed in each batch, i.e., (b) X (c);

   e. the before-control organic compound emission rate for all organic compound solvent materials employed, in pounds/day, i.e., (a) X (d);

   f. the controlled organic compound emission rate for all of the organic compound solvent materials employed, each day, by multiplying the amount in (e) 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 organic compound emission rate, i.e., (f/g), in pounds per hour (average).

IV. Reporting Requirements

1. In accordance with paragraph A.2. of the General Terms and Conditions, the permittee shall submit quarterly deviation (excursion) reports to the Director (the appropriate Ohio EPA District Office or local air agency) which include the following information for this emissions unit:

   a. an identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0. 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 15.84 lbs/day, and the actual controlled organic compound emissions rate for each such day.

   c. an identification of all 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than fifty degrees Fahrenheit below the average combustion temperature of the exhaust gases during the most recent performance test that demonstrated the emissions unit was in compliance.

   d. an identification of all three hour blocks of time (when the emission unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent performance test that demonstrated the emissions unit was in compliance.

   e. 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.

2. 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.

V. Testing Requirements

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

   a. <u>Emission Limitation</u>

      0.68 lb/hr, as an average over the batch cycle

      <u>Applicable Compliance Method</u>

Compliance shall be determined by emission testing as specified in section V.2. and the recordkeeping as specified in III.2.

b. Emission Limitation

16.32 lbs/day

Applicable Compliance Method

Compliance shall be determined by performance testing and recordkeeping as specified in III.2.

c. Emission Limitation

2.99 TPY

Applicable Compliance Method

Compliance shall be determined by the recordkeeping in III.2. and shall be the summation of the daily controlled organic emissions for the calendar year.

2. Emission Testing Requirements

The permittee shall conduct, or have conducted, emission testing on this emissions unit in accordance with the following requirements:

a. The emissions testing shall be conducted within ninety days after permit issuance.

b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates 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, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

d. The test(s) shall be conducted while the 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.

VI. Miscellaneous Requirements

None.

B. State Only Enforceable Section

I. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(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 specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P015 - Glatt Fluid Bed Coater for pharmaceuticals		Compliance with Air Toxics Policy

2. Additional Terms and Conditions

None.

II. Operational Restrictions

None.

III. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that a changed emissions unit will still satisfy the Air Toxic Policy:

   a. a description of the parameters changed (composititon 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.

IV. Reporting Requirements

None.

V. Testing Requirements

None.

VI. Miscellaneous Requirements

Air Toxic Policy Clarifying Language

1. The permit to install for this emissions unit (P015) was evaluated based o the actual materials specified by the permittee in the permit to install application. The emission limitation(s) specified in this permit was (were) established using the Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") and is (are) based on both the materials used and the design parameters of the emissions unit's exhaust system, as specified in the application. The Ohio EPA's "Air Toxic Policy" was applied for each pollutant using the SCREEN 3.0 model and comparing the predicted 1-hour maximum ground-level concentration to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worse case" each pollutant(s):

   Pollutant: IPA

   TLV (ug/m3): 981,590

   Maximum Hourly Emission Rate (lbs/hr): 0.68

   Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 797.0

   MAGLC (ug/m3): 23,371

   Physical changes or changes in the method of operation of the emissions unit that result in changes to the factors affecting the air toxic analysis could result in noncompliance with this permit to install. In order to avoid this noncompliance situation, prior to initiating any changes, permittees are required to conduct an evaluation to determine that the "Air Toxic Policy" is still satisfied. Changes that can affect the "Air Toxic Policy" include, but are not limited to, 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.)

   The Ohio EPA will not consider any of the above-mentioned as a "modification" requiring a permit to install, if the following conditions are met:

a. the change is not otherwise considered a “modification” under OAC Chapter 3745-31;

b. the permittee can continue to comply with the allowable emission limitations specified in its permit to install; and,

c. prior to the change, the applicant conducts an evaluation pursuant to the Air Toxic Policy, determines that the changed emissions unit still satisfies the Air Toxic Policy, and the permittee maintains documentation that identifies the change and the results of the application of the Air Toxic Policy for the change.

For any change to the emissions unit or its method of operation that either would require an increase in the emission limitation(s) established by this permit or would otherwise be considered a "modification" as defined in OAC rule 3745-31-01, the permittee shall obtain a final permit to install prior to the change.

Part III - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. State and Federally Enforceable Section

I. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(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 specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P016 - LEMS unit for the sealing of pharmaceutical capsules, controlled by a catalytic incinerator	OAC rule 3745-31-05(A)(3)	0.04 lb/hr as an average over the batch cycle, 0.96 lb/day, 0.18 TPY organic compunds
	OAC rule 3745-21-07(G)(2)	See A.2.a.

2. Additional Terms and Conditions

2.a The emission limitations specified in OAC rule 3745-21-07(G)(2) are less stringent than the emission limitation specified above as Best Available Technology (BAT).

II. Operational Restrictions

1. The organic compound (OC) emissions from emissions unit P016 shall be controlled through the application of a catalytic incinerator. The catalytic incinerator shall operate at a destruction efficiency of at least 98 percent.

2. The average temperature of the exhaust gases immediately before the catalyst bed, for any 3-hour block of time 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 average temperature difference across the catalyst bed, for any 3-hour block of time when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

III. Monitoring and/or Recordkeeping Requirements

1. The permittee shall operate and maintain continuous temperature monitor and recorder(s) which measure and record(s) the temperature immediately upstream and downstream of the incinerator's catalyst bed 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(s) 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 for each day:

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

   b. All 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than than 50 degrees Fahrenheit below the average temperature of the exhaust gases during the most recent performance test that demonstrated the emissions unit was in compliance.

   c. All 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent performance test that demonstrated the emissions unit was in compliance.

2. The permittee shall collect and record the following information each day when the emissions unit is in operation:

   a. the number of batches each day;

   b. the number of gallons of each organic compound solvent material in each batch;

   c. the density of the organic compound solvent material employed in each batch, (pounds/gallon);

   d. the pounds of organic compound solvent material employed in each batch, i.e., (b) X (c);

   e. the before-control organic compound emission rate for all organic compound solvent materials employed, in pounds/day, i.e., (a) X (d);

   f. the controlled organic compound emission rate for all of the organic compound solvent materials employed, each day, by multiplying the amount in (e) 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 organic compound emission rate, i.e., (f/g), in pounds per hour (average).

IV. Reporting Requirements

1. In accordance with paragraph A.2. of the General Terms and Conditions, the permittee shall submit quarterly deviation (excursion) reports to the Director (the appropriate Ohio EPA District Office or local air agency) which include the following information for this emissions unit:

   a. an identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0.04 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 0.96 lb/day, and the actual controlled organic compound emissions rate for each such day.

   c. an identification of all 3-hour blocks of time (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than fifty degrees Fahrenheit below the average combustion temperature of the exhaust gases during the most recent performance test that demonstrated the emissions unit was in compliance.

   d. an identification of all three hour blocks of time (when the emission unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent performance test that demonstrated the emissions unit was in compliance.

   e. 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.

2. 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.

V. Testing Requirements

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

   a. <u>Emission Limitation</u>

      0.04 lb/hr, as an average over the batch cycle

      <u>Applicable Compliance Method</u>

Compliance shall be determined by emission testing as specified in section V.2. and the recordkeeping as specified in III.2.

b. Emission Limitation

0.96 lb/day

Applicable Compliance Method

Compliance shall be determined by performance testing and recordkeeping as specified in III.2.

c. Emission Limitation

0.18 TPY

Applicable Compliance Method

Compliance shall be determined by the recordkeeping in III.2. and shall be the summation of the daily controlled organic emissions for the calendar year.

2. Emission Testing Requirements

The permittee shall conduct, or have conducted, emission testing on this emissions unit in accordance with the following requirements:

a. The emissions testing shall be conducted within ninety days after permit issuance.

b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates 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, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

d. The test(s) shall be conducted while the 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.

VI. Miscellaneous Requirements

None.

B. State Only Enforceable Section

I. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(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 specified in narrative form following the table.

Operations, Property, and/or Equipment	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
P016 - LEMS unit for the sealing of pharmaceutical capsules.		Compliance with Air Toxics Policy

2. Additional Terms and Conditions

None.

II. Operational Restrictions

None.

III. Monitoring and/or Recordkeeping Requirements

1. The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that a changed emissions unit will still satisfy the Air Toxic Policy:

   a. a description of the parameters changed (composititon 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.

IV. Reporting Requirements

None.

V. Testing Requirements

None.

VI. Miscellaneous Requirements

Air Toxic Policy Clarifying Language

1. The permit to install for this emissions unit (P016) was evaluated based on the actual materials specified by the permittee in the permit to install application. The emission limitation(s) specified in this permit was (were) established using the Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") and is (are) based on both the materials used and the design parameters of the emissions unit's exhaust system, as specified in the application. The Ohio EPA's "Air Toxic Policy" was applied for each pollutant using the SCREEN 3.0 model and comparing the predicted 1-hour maximum ground-level concentration to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worse case" each pollutant(s):

   Pollutant: Ethanol

   TLV (ug/m3): 1,840,000

   Maximum Hourly Emission Rate (lbs/hr): 0.04

   Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 11.7

   MAGLC (ug/m3): 43,809

   Physical changes or changes in the method of operation of the emissions unit that result in changes to the factors affecting the air toxic analysis could result in noncompliance with this permit to install. In order to avoid this noncompliance situation, prior to initiating any changes, permittees are required to conduct an evaluation to determine that the "Air Toxic Policy" is still satisfied. Changes that can affect the "Air Toxic Policy" include, but are not limited to, 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.)

The Ohio EPA will not consider any of the above-mentioned as a “modification” requiring a permit to install, if the following conditions are met:

a. the change is not otherwise considered a “modification” under OAC Chapter 3745-31;

b. the permittee can continue to comply with the allowable emission limitations specified in its permit to install; and,

c. prior to the change, the applicant conducts an evaluation pursuant to the Air Toxic Policy, determines that the changed emissions unit still satisfies the Air Toxic Policy, and the permittee maintains documentation that identifies the change and the results of the application of the Air Toxic Policy for the change.

For any change to the emissions unit or its method of operation that either would require an increase in the emission limitation(s) established by this permit or would otherwise be considered a "modification" as defined in OAC rule 3745-31-01, the permittee shall obtain a final permit to install prior to the change.

NEW SOURCE REVIEW FORM B

PTI Number: 08-04135 Facility ID: 0857171794

FACILITY NAME Eurand America Inc

FACILITY DESCRIPTION pan coater, glatt fluid bed coater, LEMS capsule sealer. CITY/TWP Vandalia

SIC CODE 2834 SCC CODE 30106011 EMISSIONS UNIT ID P014

EMISSIONS UNIT DESCRIPTION a pan coater for pharmaceuticals

DATE INSTALLED waiting for PTI

EMISSIONS: (Click on bubble help for Air Quality Descriptions)

Pollutants	Air Quality Description	Actual Emissions Rate		PTI Allowable	
		Short Term Rate	Tons Per Year	Short Term Rate	Tons Per Year
Particulate Matter					
PM_{10}					
Sulfur Dioxide					
Organic Compounds	lb/hr	0.66	2.89	0.66	2.89
Nitrogen Oxides					
Carbon Monoxide					
Lead					
Other: Air Toxics					

APPLICABLE FEDERAL RULES:

NSPS? NESHAP? PSD? OFFSET POLICY?

WHAT IS THE BAT DETERMINATION, AND WHAT IS THE BASIS FOR THE DETERMINATION?
Enter Determination Emissions are controlled by the use of a catalytic incinerator, recordkeeping, and reporting

IS THIS SOURCE SUBJECT TO THE AIR TOXICS POLICY? yes

OPTIONAL: WHAT IS THE CAPITAL COST OF CONTROL EQUIPMENT? $

TOXIC AIR CONTAMINANTS

Ohio EPA's air toxics policy applies to contaminants for which the American Conference of Governmental Industrial Hygienists (ACGIH) has a listed threshold limit value.

AIR TOXICS MODELING PERFORMED*? X YES NO

IDENTIFY THE AIR CONTAMINANTS: methanol, ethanol, IPA, acetone

NEW SOURCE REVIEW FORM B

PTI Number: 08-04135 Facility ID: 0857171794

FACILITY NAME Eurand America Inc

FACILITY DESCRIPTION pan coater, glatt fluid bed coater, LEMS capsule sealer. CITY/TWP Vandalia

SIC CODE 2834 SCC CODE 30106011 EMISSIONS UNIT ID P015

EMISSIONS UNIT DESCRIPTION Glatt Fluid Bed Coater for pharmaceuticals

DATE INSTALLED waiting for PTI

EMISSIONS: (Click on bubble help for Air Quality Descriptions)

Pollutants	Air Quality Description	Actual Emissions Rate		PTI Allowable	
		Short Term Rate	Tons Per Year	Short Term Rate	Tons Per Year
Particulate Matter					
PM_{10}					
Sulfur Dioxide					
Organic Compounds	lb/hr	0.68	2.99	0.68	2.99
Nitrogen Oxides					
Carbon Monoxide					
Lead					
Other: Air Toxics					

APPLICABLE FEDERAL RULES:

NSPS? NESHAP? PSD? OFFSET POLICY?

WHAT IS THE BAT DETERMINATION, AND WHAT IS THE BASIS FOR THE DETERMINATION?
Enter Determination

IS THIS SOURCE SUBJECT TO THE AIR TOXICS POLICY? yes

OPTIONAL: WHAT IS THE CAPITAL COST OF CONTROL EQUIPMENT? $

TOXIC AIR CONTAMINANTS

Ohio EPA's air toxics policy applies to contaminants for which the American Conference of Governmental Industrial Hygienists (ACGIH) has a listed threshold limit value.

AIR TOXICS MODELING PERFORMED*? X YES NO

IDENTIFY THE AIR CONTAMINANTS: cyclohexane, ethanol, IPA, acetone

NEW SOURCE REVIEW FORM B

PTI Number: 08-04135 Facility ID: 0857171794

FACILITY NAME Eurand America Inc

FACILITY DESCRIPTION pan coater, glatt fluid bed coater, LEMS capsule sealer. CITY/TWP Vandalia

SIC CODE 2834 SCC CODE 30106011 EMISSIONS UNIT ID PO16

EMISSIONS UNIT DESCRIPTION LEMS unit for the sealing of pharmaceutical capsules.

DATE INSTALLED waiting for PTI

EMISSIONS: (Click on bubble help for Air Quality Descriptions)

Pollutants	Air Quality Description	Actual Emissions Rate		PTI Allowable	
		Short Term Rate	Tons Per Year	Short Term Rate	Tons Per Year
Particulate Matter					
PM_{10}					
Sulfur Dioxide					
Organic Compounds	lb/hr	0.04	0.18	0.04	0.18
Nitrogen Oxides					
Carbon Monoxide					
Lead					
Other: Air Toxics					

APPLICABLE FEDERAL RULES:

NSPS? NESHAP? PSD? OFFSET POLICY?

WHAT IS THE BAT DETERMINATION, AND WHAT IS THE BASIS FOR THE DETERMINATION?
Enter Determination

IS THIS SOURCE SUBJECT TO THE AIR TOXICS POLICY? yes

OPTIONAL: WHAT IS THE CAPITAL COST OF CONTROL EQUIPMENT? $

TOXIC AIR CONTAMINANTS

Ohio EPA's air toxics policy applies to contaminants for which the American Conference of Governmental Industrial Hygienists (ACGIH) has a listed threshold limit value.

AIR TOXICS MODELING PERFORMED*? X YES NO

IDENTIFY THE AIR CONTAMINANTS: ethanol

NEW SOURCE REVIEW FORM B

PTI Number: 08-04135 Facility ID: 0857171794

FACILITY NAME Eurand America Inc

FACILITY DESCRIPTION	pan coater, glatt fluid bed coater, LEMS capsule sealer.	CITY/TWP	Vandalia

Please describe any hard copy information is being submitted with this recommendation (Please send hard copy information to Pam McGraner, DAPC Central Office - Air Quality Modeling and Planning):

Modeling

Please provide any additional permit specific notes as you deem necessary:

This permit is written in draft to ensure the control requirements are federally enforceable.

Permit To Install Synthetic Minor Write-Up

Source Description: Pan Coater, Glatt Fluid Bed Coater, LEMS (coaters for pharmaceuticals)

Facility Emissions and Attainment Status: Including the allowable emissions of this PTI, the potential emissions of OC from this facility will exceed 100 tons/year.

Source Emissions: The total OC emissions for this PTI are equal to 6.06 tons/year. A pan coater (P014) uses a drum to contain the pharmaceuticals to be coated. The drum rates while a coating is sprayed into the chamber. The process can be either aqueous or solvent based. Solvents that could be used are methanol (HAP), ethanol, isopropyl alcohol or acetone. Controlled OC emissions from P014 are equal to 2.89 tons/year.

A Gratt Fluid Bed Coater, (P015) is similar to the existing fluid bed coater. The pharmaceuticals are placed in the unit and air is blown up from the bottom of the mixer and coatings are sprayed onto the substrate. Solvents used in the process are cyclohexane, ethanol, isopropyl alcohol or acetone. Controlled OC emissions from P015 are equal to 2.99 tons/year

A LEMs coater (P016) is a process that seals pharmaceutical capsules. A small amount of solvent is sprayed on each capsule and allowed to soften the gel. The fluid is suctioned to remove excess fluid and heated air (60 degrees C.) is blown across the capsules during a one minute cycle to complete the melting and fusion of the two gelatin layers. When the product returns to room temperature, the capsule is sealed. The solvent is a 50/50 mixture of ethanol/water. Controlled OC emissions from P016 are equal to 0.18 ton/year.

Conclusion: a catalytic oxidizer will be installed for these sources. Control efficiency will be 98% and the unit will be designed to handle twice the level of emissions for these sources, giving Eurand the control capacity to add more sources in the future. By design, the units are totally enclosed.

NSR Discussion

The permit will be written in draft to federally enforce the control efficiency of the catalytic oxidizer. The permit will limit emissions from the three units to 6.06 tons/year OC. Methanol emissions will also be controlled by 98%. If the emissions from these units were not federally enforceable, the uncontrolled emissions would subject this facility to Title V (above 100 TPY OC and above 10 TPY single HAPs) and PSD (uncontrolled emissions greater than 250 TPY)

NEW SOURCE REVIEW FORM B

PTI Number: 08-04135 Facility ID: 0857171794

FACILITY NAME Eurand America Inc

FACILITY DESCRIPTION	pan coater, glatt fluid bed coater, LEMS capsule sealer.	CITY/TWP	Vandalia

The permit to install does not include language for total enclosure. Enclosure is by design. Emissions are vented to a catalytic oxidizer.

Modeling has been conducted and it has been determined the emission levels are below the MAGLC for ethanol, methanol, isopropyl alcohol, acetone, and cyclohexane.

Calculations:

P014 , Pan Coater
solvent usage = 33.0 lbs/hr
Solvent used are methanol, ethanol, IPA, or acetone (one of the four is used at a time)
Potential Emissions:
(33.0 #/hr)(8760 hr/yr) / 2000 lb/ton = 144.5 TPY (methanol, also a HAP)
(33.0 #/hr)(24 hrs/day) = 792.0 #/day

emissions are controlled with a catalytic incinerator = 98% control
(33.0 #/hr)(1.0 - 0.98) = 0.66 lb/hr
(0.66 lb/hr)(8760 hr/yr) = 2.89 ton/yr
(0.66 lb/hr)(24 hr/day) = 15.84 lbs/day

P015, Glatt Fluid Bed Coater
solvents used in this process are cyclohexane, ethanol, IAP, acetone
5.07 gal/hr
Densities of solvents:

cyclohexane	6.48 lb/gallon
ethanol	6.74 lb/gallon
IPA	6.55 lb/gallon
acetone	6.59 lb/gallon

Ethanol is heaviest (worst case if ethanol is used)
(5.07 lb/gallon)(6.74 lb/gallon) = 34.17 lbs/hr
(34.17 lbs/hr)(8760 hr/yr)/ 2000 lbs/ton = 149.66 ton/yr (potential)
(34.17 lbs/hr)(24 hrs/day) = 820.08 lb/day (potential)
Emissions are controlled by a catalytic incinerator - 98% control
(34.17 lbs/hr)(.02) = 0.68 lb/hr, 16.32 lbs/day
(149.66 ton/yr)(.02) = 2.99 ton/yr

P016, LEMS

NEW SOURCE REVIEW FORM B

PTI Number: 08-04135 Facility ID: 0857171794

FACILITY NAME Eurand America Inc

FACILITY DESCRIPTION	pan coater, glatt fluid bed coater, LEMS capsule sealer.	CITY/TWP	Vandalia

solvent used in this process is ethanol
Use 1.96 lb/hr ethanol
(1.96 lb/hr)(8760 hr/yr) / 2000 lb/ton = 8.58 TPY
(1.96 lb/hr)(24 hr/day) = 47.0 lbs/day
The emissions are controlled by a catalytic incinerator to reduce emission by 98%
(1.96 lb/hr)(.02) = 0.04 lb/hr
(0.04 lb/hr)(8760 hrs/yr) / 2000 lb/ton = 0.18 TPY

Please fill in the following for this permit:

TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

Pollutant	Tons Per Year
organic compounds	**6.06 TPY**