



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL
MONTGOMERY COUNTY**

CERTIFIED MAIL

Street Address:

122 S. Front Street

Lazarus Gov. Center TELE: (614) 644-3020 FAX: (614) 644-2329

Mailing Address:

Lazarus Gov. Center
P.O. Box 1049

Application No: 08-4112

DATE: December 22, 1999

Eurand America Inc.
Dwight Humbert
845 Center Drive
Vandalia, OH 45377-3129

Enclosed please find an Ohio EPA Permit to Install which will allow you to install the described source(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, I urge you to read it carefully.

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.

You are hereby notified that this action by the Director is final and may be appealed to the Ohio Environmental Review Appeals Commission pursuant to Chapter 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. It must be filed within thirty (30) days after the notice of the Directors action. A copy of the appeal must be served on the Director of the Ohio Environmental Protection Agency within three (3) days of filing with the Commission. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
236 East Town Street, Room 300
Columbus, Ohio 43215

Very truly yours,

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

cc: USEPA
REGIONAL AIR POLLUTION CONTROL AGENCY



STATE OF OHIO ENVIRONMENTAL PROTECTION AGENCY

Permit To Install

Issue Date: December 22,
1999

Terms and
Conditions

Effective Date: December 22,
1999

FINAL PERMIT TO INSTALL 08-4112

Application Number: 08-4112
APS Premise Number: 0857171794
Permit Fee: **\$400**
Name of Facility: Eurand America Inc.
Person to Contact: Dwight Humbert
Address: 845 Center Drive
Vandalia, OH 45377-3129

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

Description of proposed emissions unit(s):
**BEAD PREPARATION AND COATING OF PHARMACEUTICALS, ENCLOSED GRANULATOR,
AND FOUR DRYING OVENS.**

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. 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 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 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. Records Retention Requirements

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.

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections, conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. 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 verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

5. 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 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. 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 emissions unit(s) that is (are) served by such control system(s).

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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).

12. 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.

13. Source Operation and Operating Permit Requirements After Completion of Construction

This facility is permitted to operate each source described by this Permit to Install for a period of up to one year from the date the source commenced operation. This 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 emissions unit(s) covered by this permit.

14. Construction Compliance Certification

Eurand America Inc.
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December 22, 1999

Facility ID: **0857171794**

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.

15. 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.

B. 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

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	.35

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. 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.

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Limitations/Control Measures</u>	<u>Emissions</u>
Bead Preparation and coating of pharmaceuticals, enclosed granulator, extruder, spheronizer, and four drying ovens with thermal oxidizer.	OAC rule 3745-31-05(A)(3) OAC rule 3745-21-07(G)(2)	.08 lbs/hr as an average over the batch cycle, 1.92 lbs/day, .35 TPY OC 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 limitations specified above.

B. Operational Restrictions

- 1. The organic compound (OC) emissions from emissions unit P013 shall be controlled through the application of a thermal oxidizer. The thermal oxidizer shall operate at a destruction efficiency of at least 98 percent.
- 2. The average combustion temperature within the thermal oxidizer, 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.

3. When the emissions unit is in operation, the emissions unit shall be totally enclosed such that OC emissions are captured and contained for discharge through the thermal oxidizer. Compliance with the following criteria, identified by USEPA Method 204, shall satisfy the total enclosure requirement:
 - a. Any natural draft opening (NDO) shall be at least four equivalent opening diameters from each OC emitting point unless otherwise specified by the Administrator.
 - b. The total area of all NDO's 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 NDO's shall be at least 3,600 m/hr (200 fpm). The direction of air flow through all NDO's shall be into the enclosure.
 - d. All access doors and windows whose areas are not included in section (b) and are not included in the calculation in section (c) shall be closed during routine operation of the process.
 - e. All OC emissions must be captured and contained for discharge through a control device.
4. The permanent total enclosure shall be maintained under negative pressure, at a minimum pressure differential that is not less than 0.007 inches of water, as a three hour average, whenever the emissions unit is in operation.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall operate and maintain a continuous temperature monitor and recorder which measures and records the combustion temperature within the thermal oxidizer when the emissions unit is in operation. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

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

- a. All 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer, when the emissions unit was in operation, was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
 - b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information each day when the emissions unit is in operation:
- a. the number of sub-batches each day;
 - b. the number of gallons of each organic compound solvent material in each sub-batch;
 - c. the density of the organic compound solvent material employed in each sub-batch, (pounds/gallon);
 - d. the pounds of organic compound solvent material employed in each sub-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).
3. The permittee shall install, maintain and operate monitoring device(s) and a recorder which simultaneously measure and record the differential pressure between the inside and outside of the permanent total enclosure. The monitoring and recording devices shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, instructions and operating manuals.

When the emissions unit is in operation, the permittee shall maintain records of all three hour blocks of time during which the permanent total enclosure was not maintained at or above the minimum pressure differential of 0.007 inches of water, as a three hour average.

D. 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 .08 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 1.92 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - c. An identification of all 3-hour blocks of time during which the average combustion temperature within the thermal oxidizer was more than fifty degrees Fahrenheit below the average combustion temperature during the most recent performance test that the emissions unit was in compliance.
 - d. An identification of all three hour blocks of time during which the permanent total enclosure was not maintained at the minimum pressure differential of 0.007 inches of water, as a three hour average, when the emissions unit was in operation.

E. Testing Requirements

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

.08 lb/hr, as an average over the batch cycle

Applicable Compliance Method

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

1.b. Emission Limitation

1.92 lbs/day

Applicable Compliance Method

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

1.c. Emission Limitation

.35 TPY

Applicable Compliance Method

Compliance shall be determined by the recordkeeping in C.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

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capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency.

- e. The capture efficiency shall be determined using Methods 204 through 204F, as specified in 40 CFR Part 51, Appendix M, or the permittee may request to use an alternative method or procedure for the determination of capture efficiency in accordance with the USEPA's "Guidelines for Determining Capture Efficiency," dated January 9, 1995. (The Ohio EPA will consider the request, including an evaluation of the applicability, necessity, and validity of the alternative, and may approve the use of the alternative if such approval does not contravene any other applicable requirement.) The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 or the approved alternative test protocol (e.g., "the mass balance protocol approved on 10/25/95"). The test methods and procedures selected shall be based on a consideration of the diversity of the organic species present and their total concentration, and on a consideration of the potential presence of interfering gases.

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.

EuranPTI A₁**December 22, 1999**Emissions Unit ID: **P013**

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

None