



State of Ohio Environmental Protection Agency

RE: FINAL PERMIT TO INSTALL CERTIFIED MAIL
FRANKLIN COUNTY

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: 01-08002

DATE: 3/15/00

Roxane Laboratories, Inc.
Kelly Lewis
P.O. Box 16532 1809 Wilson Road
Columbus, OH 43216

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

CDO



STATE OF OHIO ENVIRONMENTAL PROTECTION AGENCY

Permit To Install

Issue Date: 3/15/00

FINAL PERMIT TO INSTALL 01-08002

Application Number: 01-08002
APS Premise Number: 0125040886
Permit Fee: **\$200**
Name of Facility: Roxane Laboratories, Inc.
Person to Contact: Kelly Lewis
Address: P.O. Box 16532 1809 Wilson Road
Columbus, OH 43216

Location of proposed air contaminant source(s) [emissions unit(s)]:

**330 Oak Street
Columbus, Ohio**

Description of proposed emissions unit(s):

pharmaceutical manufacturing and packaging operation

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

Roxane Laboratories, Inc.
PTI Application: 01-08002
Issued: 3/15/00

Facility ID: 0125040886

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

Roxane Laboratories, Inc.
PTI Application: 01-08002
Issued: 3/15/00

Facility ID: 0125040886

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>
Organic Compounds	5.50
Particulate	0.1

PART II: SPECIAL TERMS AND CONDITIONS

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 Emissions Limitations/Control Measures</u>
pharmaceutical manufacturing and packaging operation	OAC rule 3745-17-07(A)(1)	This limitation is less restrictive than A.2.b.
	OAC rule 3745-17-11(C)	This limitation is less restrictive than A.2.c. and OAC rule 3745-31-05.
	OAC rule 3745-21-07(G)	Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using nonphotochemically reactive materials. See A.2.a. below.
	OAC rule 3745-31-05(A)(3)	Particulate matter emissions shall not exceed 0.1 lb/hr and 0.1 ton/yr. See A.2.b. and A.2.c. below. Organic compound emissions shall not exceed 10 lbs/hr and 5.50 tons/yr.

2. Additional Terms and Conditions

- 2.a The permittee shall not use any photochemically reactive as defined in OAC rule 3745-21-01(C).
- 2.b There shall be no visible emissions from the emissions unit.

- 2.c** The emissions from the emissions unit shall vent to a baghouse, pleated filter and HEPA filter (with a composite control efficiency of 99.99%). These control devices are considered an inherent physical limitation since they are used to ensure that the company can account for the total volume of powder use in the process, by weight. The FDA and DEA require total accountability of the pharmaceuticals manufactured by Roxane Laboratories. Due to this inherent physical limitation, monitoring for visible emissions is unnecessary.

B. Operational Restrictions

1. The permittee shall not employ an alcohol with a organic compound content greater than 98%, by weight.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall maintain daily records of the following information:
- the number of gallons of alcohol employed;
 - the density of the alcohol, in pounds per gallon;
 - the percent of organic compounds, by weight;
 - the total number of hours the emissions unit was in operation;
 - the total uncontrolled organic compound emissions, in pounds per day; and
 - the average hourly uncontrolled organic compound emission rate for alcohol, in pounds per hour (average).
2. The permittee shall maintain daily records that document any time when the baghouse, pleated filter and/or HEPA filter were not in service while the emissions unit was in operation.
3. The permittee shall collect and record the following information for each change where the air toxic modeling was required pursuant to the Air Toxic Policy:
- background data that describes the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.); and
 - a copy of the resulting computer model runs that show the results of the application of the

Air Toxic Policy for the change.

D. Reporting Requirements

1. The permittee shall submit deviation (excursion) reports which identify each day during which the average hourly total organic compound emissions exceeded 10.0 pounds per hour, and the actual average hourly organic compound emissions for each such day. These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit.
2. The permittee shall submit annual reports which specify the organic compound emissions for the previous calendar year. These reports shall be submitted by January 31 of each year.
3. The permittee shall notify the Director (the appropriate District Office or local air agency) in writing of any daily record showing that the baghouse, pleated filter and/or HEPA filter were not in service when the emissions unit was in operation. The notification shall include a copy of such record and shall be sent to the Director (the appropriate District Office or local air agency) within 30 days after the event occurs.
4. The permittee shall submit deviation (excursion) reports which identify each day during which any photochemically reactive materials were employed. These reports are due by the dates described in Part 1 - General Terms and Conditions of this permit..

E. Testing Requirements

1. Compliance with the emission limitation(s) in Section A of these terms and conditions shall be determined in accordance with the following method(s):
 - a. Emission Limitation -
no visible emissions

Applicable Compliance Method -
If required, compliance shall be determined through visible emissions observations performed in accordance with the procedures specified in OAC rule 3745-17-03(B)(4).
 - b. Emission Limitation -
Particulate emissions shall not exceed 0.1 lb/hr and 0.1 ton/yr.

Applicable Compliance Method -
Compliance with the hourly emission limitation shall be demonstrated by multiplying the maximum hourly solids usage of 793 lbs/hr by the non-recovered product loss of 0.25

Emissions Unit ID: **P002**

(emissions factor determined by company mass balance) and 0.0001 (control factor). This value represents the potential-to-emit.

- c. Emission Limitation -
 Organic compound emissions shall not exceed 10 lbs/hr.

Applicable Compliance Method -
 Compliance shall be demonstrated by multiplying the density of the alcohol by the daily alcohol usage (in gallons) and the percent of organic compounds, by weight, and then dividing by the hours of operation.

Formulation data derived from MSDS or USEPA Method 24 shall be used to determine the organic compound content of the alcohol.

- d. Emission Limitation -
 Organic compound emissions shall not exceed 5.5 tons/yr.

Applicable Compliance Method -
 Compliance shall be demonstrated by summing the total uncontrolled organic compound emissions, in pounds per day, for the calendar year and converting to tons per year.

F. Miscellaneous Requirements

Air Toxic Policy Clarifying Language

This permit allows the use of materials (typically coatings and cleanup materials) specified by the permittee in the permit to install application for this emissions unit. To fulfill the best available technology requirements of (OAC) rule 3745-31-05 and to ensure compliance with OAC rule 3745-15-07 (Air Pollution Nuisances Prohibited), the emission limitation(s) specified in this permit was (were) established using the Ohio EPA's "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 each pollutant:

Pollutant: ethyl alcohol

TLV (ug/m3): 1,880,000

Maximum Hourly Emission Rate (lbs/hr): 8.7

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 1,275

MAGLC (ug/m3): 44,762

OAC Chapter 3745-31 requires permittees to apply for and obtain a new or modified permit to install prior to making a "modification" as defined by the OAC rule 3745-31-01. The permittee is hereby advised that the following changes to the process may be determined to be a "modification":

- 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 specified in the above table;
- b. changes to the emissions unit or its exhaust parameters (e.g., increased emission rate [not including an increase in an "allowable" emission limitation specified in the terms and conditions of this permit], reduced exhaust gas flow rate, and decreased stack height);
- c. changes in the composition of the materials used, or use of new materials, that would result in the emission of an air contaminant not previously permitted; and
- d. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant that has a listed TLV.

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.

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Roxane Laboratories, Inc.
PTI Application: 01 09007
Issued

Facility ID: 0125040886

Emissions Unit ID: P002

Roxan

PTI A

Issued: 3/15/00

Emissions Unit ID: P002

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):

New Source Review Form B, Emissions Verification and Analysis, Toxic Impact Analysis, New Source Review and Modeling

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

NONE

Permit To Install Synthetic Minor Write-Up

NONE

Please fill in the following for this permit:

TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

<u>Pollutant</u>	<u>Tons Per Year</u>
Organic Compounds	5.50
Particulate	0.1