



State of Ohio Environmental Protection Agency

Street Address:

Mailing Address:

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

Lazarus Gov.  
Center

RE: **FINAL PERMIT TO INSTALL MODIFICATION** CERTIFIED MAIL  
FRANKLIN COUNTY  
Application No: 01-06309

DATE: 2/26/2002

Roxane Laboratories  
Kelly Lewis  
1809 Wilson Rd  
Columbus, OH 43216

Enclosed Please find a modification to the Ohio EPA Permit To Install referenced above which will modify the terms and conditions.

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,

A handwritten signature in cursive script that reads "Thomas G. Rigo".

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

CC: USEPA

CDO



**Permit To Install  
Terms and Conditions**

**Issue Date: 2/26/2002  
Effective Date: 2/26/2002**

**FINAL ADMINISTRATIVE MODIFICATION OF PERMIT TO INSTALL 01-06309**

Application Number: **01-06309**  
APS Premise Number: **0125041763**  
Permit Fee: **\$0**  
Name of Facility: **Roxane Laboratories Lewis**  
Person to Contact: **Kelly**  
Address: **1809 Wilson Rd  
Columbus, OH 43216**

Location of proposed air contaminant source(s) [emissions unit(s)]:  
**1809 Wilson Road  
Columbus, OHIO**

Description of modification:  
**Liquids Manufacturing, Cleaning Process, (4) Granulators, Fluid Bed Dryer, Roller Comp, Weighting Units, Capsule Mach.**

The above named entity is hereby granted a modification to the permit to install described above pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this modification 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 source(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 included in the application, the above described source(s) of pollutants will be granted the necessary operating permits.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

**Roxane Laboratories**

Facility ID: **0125041763**

**PTI Application: 01-06309**

**Modification Issued: 2/26/2002**

## **GENERAL PERMIT CONDITIONS**

### **TERMINATION OF PERMIT TO INSTALL**

Substantial construction for installation must take place within 18 months of the effective date of this permit. 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.

### **NOTICE OF INSPECTION**

The Director of the Ohio Environmental Protection Agency, or his authorized representatives, may enter upon the premises of the above-named applicant during construction and operation at any reasonable time for the purpose of making inspections, conducting tests, or to examine records or reports pertaining to the construction, modification or installation of the source(s) of environmental pollutants identified within this permit.

### **CONSTRUCTION OF NEW SOURCES**

The proposed source(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 source(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 Ohio Administrative Code (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 cannot meet applicable standards.

### **PERMIT TO INSTALL FEE**

In accordance with Ohio Revised Code 3745.11, the specified Permit to Install fee must be remitted within 30 days of the effective date of this permit to install.

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

### **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.

### **APPLICABILITY**

This Permit to Install is applicable only to the contaminant sources identified. Separate application must be made to the Director for the installation or modification of any other contaminant sources.

### **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.

### **PERMIT TO OPERATE APPLICATION AND OPERATION AFTER COMPLETION OF CONSTRUCTION**

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).

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.

### **SOURCE OPERATION 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 and regulations.

5

**Roxane Laboratories**

**PTI Application: 01-06309**

**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

<u>Ohio EPA Source Number</u>	<u>Source Identification Number</u>	<u>BAT Determination</u>	<u>Applicable Federal &amp; OAC Rules</u>	<u>Permit Allowable Mass Emissions and/or Control/Usage Requirements</u>
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**AIR EMISSION SUMMARY**

The air contaminant emissions units listed below comprise the Permit to Install for **Roxane Laboratories** located in **FRANKLIN** County. The emissions units listed below shall not exceed the emission limits/control requirements contained in the table. This condition in no way limits the applicability of any other state or federal regulations. Additionally, this condition does not limit the applicability of additional special terms and conditions of this permit.

<u>Ohio EPA Source Number</u>	<u>Source Identification Number</u>	<u>BAT Determination</u>	<u>Applicable Federal &amp; OAC Rules</u>	<u>Permit Allowable Mass Emissions and/or Control/Usage Requirements</u>
P001	P007	P010	P013	Source Identification <u>Description</u> Liquids Manufacturing
P005	P008	P011	P014	Cleaning Process
P006				50 liter one pot granulation
	P009	P012		

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

Ohio EPA Source Number	Source Identification Number	BAT Determination	Applicable Federal & OAC Rules	Permit Allowable Mass Emissions and/or Control/Usage Requirements
200 Liter One Pot Granulation	Fluid bed dryer/Granulators	Tablet Presses (6)	BAT Determination	Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material
600 Liter one pot granulation.	Roller Compactor		Compliance with specified limits and applicable rules; use of a cartridge dust collector with a 95% control efficiency; use of non-photochemically reactive organic material	Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.
	Dispensary/weighting units		Compliance with specified limits and applicable rules, use of a non-photochemically reactive organic material	
2000 liter one pot granulation	Capsule Machines (2)		Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of non-photochemically reactive organic material	Compliance with specified limits and applicable rules; use of

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

<u>Ohio EPA Source Number</u>	<u>Source Identification Number</u>	<u>BAT Determination</u>	<u>Applicable Federal &amp; OAC Rules</u>	<u>Permit Allowable Mass Emissions and/or Control/Usage Requirements</u>
a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.	a non-photochemically reactive organic material.  Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.  Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.	material.  Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.	Applicable Federal & OAC Rules  3745-31-05 3745-21-07 (G)(9) 3745-17-11 3745-17-05  3745-31-05 3745-21-07 (G)(9)  3745-31-05 3745-21-07 (G)(9) 3745-17-07 3745-17-11	3745-31-05 3745-21-07 (G)(9) 3745-17-07 3745-17-11  3745-31-05 3745-21-07 (G)(9) 3745-17-07 3745-17-11
Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.	Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.		3745-31-05 3745-21-07 (G)(9) 3745-17-07 3745-17-11	3745-31-05 3745-17-07 3745-17-11
Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.	Compliance with specified limits and applicable rules; use of a cartridge dust collector with 99% control efficiency; use of a non-photochemically reactive organic material.		3745-31-05 3745-21-07 (G)(9) 3745-17-07 3745-17-11	3745-31-05 3745-17-07 3745-17-11

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

<u>Ohio EPA Source Number</u>	<u>Source Identification Number</u>	<u>BAT Determination</u>	<u>Applicable Federal &amp; OAC Rules</u>	<u>Permit Allowable Mass Emissions and/or Control/Usage Requirements</u>
	05		terms and conditions.	
3745-31-05	3745-17-07	Permit Allowable Mass Emissions and/or Control/Usage <u>Requirements</u>	0.22 lb/hr PM	
3745-17-07	3745-17-11		0.42 TPY PM	0.38 lb/hr PM
3745-17-11			49.6 lbs OC/hr	1.66 TPY PM
			7.81 OC emission cap in combination with other three Granulators; no visible emissions; see additional terms and conditions.	no visible emissions
3745-31-05		0.14 lb/hr PM		
3745-17-07		0.32 TPY PM		
3745-17-11		1.90 lbs OC/hr		
		4.28 TPY OC		
		No visible emissions; see additional terms and conditions.		
3745-31-05			0.8 lb/hr PM	0.03 lb/hr PM
3745-17-07			1.5 TPY PM	0.14 TPY PM
3745-17-11		3.7 lbs OC/hr	161.87 lbs OC/hr	no visible emissions.
		8.11 TPY OC	7.81 OC emission cap in combination with other three Granulators; no visible emissions; see additional terms and conditions.	
		>0.1 lb/hr PM		0.25 lb/hr PM
		>0.1 TPY PM		1.1 TPY PM
		14.50 lbs OC/hr		No visible emissions.
		7.81 OC emission cap in combination with other three Granulators; no visible emissions; see additional terms and conditions.		
3745-31-05			0.35 lb/hr PM	
3745-17-07			1.52 TPY PM	
3745-17-11			no visible emissions	
		>0.1 lb/hr PM		
		0.15 TPY PM		
		7.76 lbs OC/hr		
		7.81 OC emission cap in combination with other three Granulators; no visible emissions; see additional	0.44 lb/hr PM	
			1.93 TPY PM	
			No visible emissions	
3745-31-				

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

**SUMMARY**  
**TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS**

<u>Pollutant</u>	<u>Tons/Year</u>
PM	8.84
OC	20.20

**REPORTING REQUIREMENTS**

Unless otherwise specified, reports required by the Permit to Install need only be submitted to OEPA Central District Office- DAPC, 3232 Alum Creek Drive, P.O. Box 1049, Columbus, Ohio 43216-1049.

**MAINTENANCE OF EQUIPMENT**

This source and its associated air pollution control system(s) shall be maintained regularly in accordance with good engineering practices and the recommendations of the respective manufacturers in order to minimize air contaminant emissions.

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

### **MALFUNCTION/ABATEMENT**

In accordance with OAC RULE 3745-15-06, any malfunction of the source(s) or associated air pollution control system(s) shall be reported immediately to the **OEPA Central District Office-DAPC, 3232 Alum Creek Drive, P.O. Box 1049, Columbus, Ohio 43216-1049.**

Except as provided by OAC Rule 3745-15-06(A)(3), scheduled maintenance of air pollution control equipment that requires the shutdown or bypassing of air pollution control system(s) must be accompanied by the shutdown of the associated air pollution sources.

### **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.

### **ADDITIONAL SPECIAL TERMS AND CONDITIONS**

#### **1. Daily Recordkeeping**

The permittee shall collect and record the following information each day for the solutions used in cleanup and granulating processes associated with four Granulators, cleaning process, and liquids manufacturing.

- A. The company identification for each cleanup and granulating organic liquid material (excluding food additives and flavorings) employed;
- B. Documentation on whether or not each cleanup and granulating organic liquid material (excluding food additives and flavorings) is a photochemically reactive material;
- C. The number of gallons of each cleanup and granulating organic liquid material (excluding food activities and flavorings) employed;
- D. The organic compound content of each cleanup and granulating organic liquid material (excluding food additives and flavorings) employed;
- E. The uncontrolled organic compound emission rate for each cleanup and granulating organic liquid material (excluding food additives and flavorings), in pounds per day;

**Roxane Laboratories**  
**PTI Application: 01-06309**  
**Modification Issued: 2/26/2002**

Facility ID: **0125041763**

- F. The total uncontrolled organic compound emission rate for all cleanup and granulating organic liquid materials (excluding food additives and flavorings), in pounds per day;
- G. The total number of hours the emissions unit was in operation; and
- H. The average hourly uncontrolled organic compound emission rate for all cleanup and granulating organic liquid materials (excluding food additives and flavorings), i.e., (g) / (h), in pounds per hour (average).

2. **Notification of Exceedance**

These records, as well as any supporting calculations, analyses and computations, shall be retained at the facility for a period of not less than three years and shall be made available to the Director or any authorized representative of the director for review upon verbal or written request.

This facility shall notify the Central District Office of any hourly records showing exceedances of permitted OC limits. A copy of such records detailing the exceedance (s) and the corrective action taken shall be sent to the Central District Office within forty five days after the exceedance (s) occurred.

3. **Two-Year Transition Period**

Facilities that are potential major Title V facilities, but have actual emissions that are less than fifty percent of the major threshold, may choose to delay obtaining federally enforceable conditions in a Federally enforceable state operating Permit (FESOP) for up to two years and operate as a non-Title V facility. Eligible participating facilities must maintain adequate records on site to demonstrate that emissions are maintained below these thresholds for the entire facility.

A person owning or operating a facility that qualifies, who intends to delay obtaining a FESOP, must notify the Ohio EPA in writing (only once). Please submit this notification by May 15, 1995 or immediately after the determination.