State of Ohio Environmental Protection Agency

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Columbus, OH 43216-1049

Certified Mail

12/29/2008

No	TOXIC REVIEW
No	PSD
Yes	SYNTHETIC MINOR
No	CEMS
No	MACT
No	NSPS
No	NESHAPS
No	NETTING
No	MAJOR NON-ATTAINMENT
No	MODELING SUBMITTED

JEFFREY GERBER
BARR LABORATORIES, INC.
225 SUMMIT AVE
MONTVALE, NJ 07645

RE: FINAL AIR POLLUTION PERMIT-TO-INSTALL AND OPERATE
Facility ID: 1431072038
Permit Number: P0098460
Permit Type: Renewal
County: Hamilton

Dear Permit Holder:

Enclosed please find a final Air Pollution Permit-to-Install and Operate ("PTIO") which will allow you to install, modify, and/or operate the described emissions unit(s) in the manner indicated in the permit. Because this permit contains conditions and restrictions, please read it very carefully.

Ohio EPA maintains a document entitled "Frequently Asked Questions about the PTIO". The document can be downloaded from the DAPC Web page, www.epa.state.oh.us/dapc, from the "Permits" link. This document contains additional information related to your permit, such as what activities are covered under the PTIO, who has enforcement authority over the permit and Ohio EPA's authorization to inspect your facility and records. Please contact the Office of Compliance Assistance and Pollution Prevention at (614) 644-3469 if you need assistance.

The issuance of this PTIO is a final action of the Director and may be appealed to the Environmental Review Appeals Commission ("ERAC") under Section 3745.04 of the Ohio Revised Code. The appeal must be in writing and describe the action complained of and the grounds for the appeal. The appeal must be filed with the ERAC within thirty (30) days after notice of the Director's action. A filing fee of $70.00 must be submitted to the ERAC with the appeal, although the ERAC, has discretion to reduce the amount of the filing fee if you can demonstrate (by affidavit) that payment of the full amount of the fee would cause extreme hardship. If you file an appeal of this action, you must notify Ohio EPA of the filing of the appeal (by providing a copy to the Director) within three (3) days of filing your appeal with the ERAC. Ohio EPA requests that a copy of the appeal also be provided to the Ohio Attorney General's Office, Environmental Enforcement Section. An appeal may be filed with the ERAC at the following address:

Environmental Review Appeals Commission
309 South Fourth Street, Room 222
Columbus, OH 43215

If you have any questions regarding this permit, please contact the Hamilton County Dept. of Environmental Services. This permit has been posted to the Division of Air Pollution Control (DAPC) Web page www.epa.state.oh.us/dapc.

Sincerely,

Michael W. Ahern

Michael W. Ahern, Manager
Permit Issuance and Data Management Section, DAPC

Cc: HCDOES

State of Ohio Environmental Protection Agency
Division of Air Pollution Control

FINAL

Air Pollution Permit-to-Install and Operate
for
BARR LABORATORIES, INC.

Facility ID: 1431072038
Permit Number: P0098460
Permit Type: Renewal
Issued: 12/29/2008
Effective: 12/29/2008
Expiration: 12/29/2013

State of Ohio Environmental Protection Agency
Division of Air Pollution Control

Air Pollution Permit-to-Install and Operate
for
BARR LABORATORIES, INC.

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Authorization

Facility ID: 1431072038
Application Number(s): A0030129
Permit Number: P0098460
Permit Description: Fluidized Bed Granulator
Permit Type: Renewal
Permit Fee: $0.00
Issue Date: 12/29/2008
Effective Date: 12/29/2008
Expiration Date: 12/29/2013
Permit Evaluation Report (PER) Annual Date: Jan 1 - Dec 31, Due Feb 15

This document constitutes issuance to:

BARR LABORATORIES, INC.
5040 LESTER RD.
CINCINNATI, OH 45213

of a Permit-to-Install and Operate for the emissions unit(s) identified on the following page.

Ohio EPA District Office or local air agency responsible for processing and administering your permit:

Hamilton County Dept. of Environmental Services
250 William Howard Taft Pkwy.
Cincinnati, OH 45219-2660
(513)946-7777

The above named entity is hereby granted this Permit-to-Install and Operate for the air contaminant source(s) (emissions unit(s)) listed in this section 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 described emissions unit(s) will operate in compliance with applicable State and federal laws and regulations.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Chris Korleski
Director

Authorization (continued)

Permit Number: P0098460
Permit Description: Fluidized Bed Granulator

Permits for the following emissions unit(s) or groups of emissions units are in this document as indicated below:

Emissions Unit ID:	**P010**
Company Equipment ID:	WSG-690
Superseded Permit Number:	
General Permit Category and Type:	Not Applicable

A. Standard Terms and Conditions

1. **What does this permit-to-install and operate ("PTIO") allow me to do?**

   This permit allows you to install and operate the emissions unit(s) identified in this PTIO. You must install and operate the unit(s) in accordance with the application you submitted and all the terms and conditions contained in this PTIO, including emission limits and those terms that ensure compliance with the emission limits (for example, operating, recordkeeping and monitoring requirements).

2. **Who is responsible for complying with this permit?**

   The person identified on the "Authorization" page, above, is responsible for complying with this permit until the permit is revoked, terminated, or transferred. "Person" means a person, firm, corporation, association, or partnership. The words "you," "your," or "permittee" refer to the "person" identified on the "Authorization" page above.

   The permit applies only to the emissions unit(s) identified in the permit. If you install or modify any other equipment that requires an air permit, you must apply for an additional PTIO(s) for these sources.

3. **What records must I keep under this permit?**

   You must keep all records required by this permit, including monitoring data, test results, strip-chart recordings, calibration data, maintenance records, and any other record required by this permit for five years from the date the record was created. You can keep these records electronically, provided they can be made available to Ohio EPA during an inspection at the facility. Failure to make requested records available to Ohio EPA upon request is a violation of this permit requirement.

4. **What are my permit fees and when do I pay them?**

   There are two fees associated with permitted air contaminant sources in Ohio:

   - PTIO fee. This one-time fee is based on a fee schedule in accordance with Ohio Revised Code (ORC) section 3745.11, or based on a time and materials charge for permit application review and permit processing if required by the Director.

     You will be sent an invoice for this fee after you receive this PTIO and payment is due within 30 days of the invoice date. You are required to pay the fee for this PTIO even if you do not install or modify your operations as authorized by this permit.

   - Annual emissions fee. Ohio EPA will assess a separate fee based on the total annual emissions from your facility. You self-report your emissions in accordance with Ohio Administrative Code (OAC) Chapter 3745-78. This fee assessed is based on a fee schedule in ORC section 3745.11 and funds Ohio EPA's permit compliance oversight activities. For facilities that are permitted as synthetic minor sources, the fee schedule is adjusted annually for inflation. Ohio EPA will notify you when it is time to report your emissions and to pay your annual emission fees.

5. **When does my PTIO expire, and when do I need to submit my renewal application?**

   This permit expires on the date identified at the beginning of this permit document (see "Authorization" page above) and you must submit a renewal application to renew the permit. Ohio EPA will send a renewal notice to you approximately six months prior to the expiration date of this permit. However, it is very important that you submit a complete renewal permit application (postmarked prior to expiration of this permit) even if you do not receive the renewal notice.

If a complete renewal application is submitted before the expiration date, Ohio EPA considers this a timely application for purposes of ORC section 119.06, and you are authorized to continue operating the emissions unit(s) covered by this permit beyond the expiration date of this permit until final action is taken by Ohio EPA on the renewal application.

6. What happens to this permit if my project is delayed or I do not install or modify my source?

This PTIO expires 18 months after the issue date identified on the "Authorization" page above unless otherwise specified if you have not (1) started constructing the new or modified emission sources identified in this permit, or (2) entered into a binding contract to undertake such construction. This deadline can be extended by up to 12 months, provided you apply to Ohio EPA for this extension within a reasonable time before the 18-month period has ended and you can show good cause for any such extension.

7. What reports must I submit under this permit?

An annual permit evaluation report (PER) is required in addition to any malfunction reporting required by OAC rule 3745-15-06 or other specific rule-based reporting requirement identified in this permit. Your PER due date is identified in the Authorization section of this permit.

8. If I am required to obtain a Title V operating permit in the future, what happens to the operating provisions and PER obligations under this permit?

If you are required to obtain a Title V permit under OAC Chapter 3745-77 in the future, the permit-to-operate portion of this permit will be superseded by the issued Title V permit. From the effective date of the Title V permit forward, this PTIO will effectively become a PTI (permit-to-install) in accordance with OAC rule 3745-31-02(B). The following terms and conditions will no longer be applicable after issuance of the Title V permit: Section B, Term 1.b) and Section C, for each emissions unit, Term a)(2).

The PER requirements in this permit remain effective until the date the Title V permit is issued and is effective, and cease to apply after the effective date of the Title V permit. The final PER obligation will cover operations up to the effective date of the Title V permit and must be submitted on or before the submission deadline identified in this permit on the last day prior to the effective date of the Title V permit.

9. What are my obligations when I perform scheduled maintenance on air pollution control equipment?

You must perform scheduled maintenance of air pollution control equipment in accordance with OAC rule 3745-15-06(A). If scheduled maintenance requires shutting down or bypassing any air pollution control equipment, you must also shut down the emissions unit(s) served by the air pollution control equipment during maintenance, unless the conditions of OAC rule 3745-15-06(A)(3) are met. Any emissions that exceed permitted amount(s) under this permit (unless specifically exempted by rule) must be reported as deviations in the annual permit evaluation report (PER), including nonexempt excess emissions that occur during approved scheduled maintenance.

10. Do I have to report malfunctions of emissions units or air pollution control equipment? If so, how must I report?

If you have a reportable malfunction of any emissions unit(s) or any associated air pollution control system, you must report this to the Hamilton County Dept. of Environmental Services in accordance with OAC rule 3745-15-06(B). Malfunctions that must be reported are those that result in emissions that exceed permitted emission levels. It is your responsibility to evaluate control equipment breakdowns and operational upsets to determine if a reportable malfunction has occurred.

If you have a malfunction, but determine that it is not a reportable malfunction under OAC rule 3745-15-06(B), it is recommended that you maintain records associated with control equipment breakdown or process upsets. Although it is not a requirement of this permit, Ohio EPA recommends that you maintain records for non-reportable malfunctions.

11. Can Ohio EPA or my local air agency inspect the facility where the emission unit(s) is/are located?

Yes. Under Ohio law, the Director or his authorized representative may inspect the facility, conduct tests, examine records or reports to determine compliance with air pollution laws and regulations and the terms and conditions of this permit. You must provide, within a reasonable time, any information Ohio EPA requests either verbally or in writing.

12. What happens if one or more emissions units operated under this permit is/are shut down permanently?

Ohio EPA can terminate the permit terms associated with any permanently shut down emissions unit. "Shut down" means the emissions unit has been physically removed from service or has been altered in such a way that it can no longer operate without a subsequent "modification" or "installation" as defined in OAC Chapter 3745-31.

You should notify Ohio EPA of any emissions unit that is permanently shut down by submitting a certification that identifies the date on which the emissions unit was permanently shut down. The certification must be submitted by an authorized official from the facility. You cannot continue to operate an emission unit once the certification has been submitted to Ohio EPA by the authorized official.

You must comply with all recordkeeping and reporting for any permanently shut down emissions unit in accordance with the provisions of the permit, regulations or laws that were enforceable during the period of operation, such as the requirement to submit a PER, air fee emission report, or malfunction report. You must also keep all records relating to any permanently shutdown emissions unit, generated while the emissions unit was in operation, for at least five years from the date the record was generated.

Again, you cannot resume operation of any emissions unit certified by the authorized official as being permanently shut down without first applying for and obtaining a permit pursuant to OAC Chapter 3745-31.

13. Can I transfer this permit to a new owner or operator?

You can transfer this permit to a new owner or operator. If you transfer the permit, you must follow the procedures in OAC Chapter 3745-31, including notifying Ohio EPA or the local air agency of the

change in ownership or operator. Any transferee of this permit must assume the responsibilities of the transferor permit holder.

14. Does compliance with this permit constitute compliance with OAC rule 3745-15-07, "air pollution nuisance"?

This permit and OAC rule 3745-15-07 prohibit operation of the air contaminant source(s) regulated under this permit in a manner that causes a nuisance. Ohio EPA can require additional controls or modification of the requirements of this permit through enforcement orders or judicial enforcement action if, upon investigation, Ohio EPA determines existing operations are causing a nuisance.

15. What happens if a portion of this permit is determined to be invalid?

If a portion of this permit is determined to be invalid, the remainder of the terms and conditions remain valid and enforceable. The exception is where the enforceability of terms and conditions are dependent on the term or condition that was declared invalid.

B. Facility-Wide Terms and Conditions

1. This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

   a) For the purpose of a permit-to-install document, the facility-wide terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

      (1) None.

   b) For the purpose of a permit-to-operate document, the facility-wide terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

      (1) None.

C. Emissions Unit Terms and Conditions

1. P010, WSG-690

Operations, Property and/or Equipment Description:

Fluidized Bed Granulator with fabric filter

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. b)(1)e, b)(1)g.

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. b)(1)b., b)(1)e., c)(2), d)(2)c., d)(2)d, d)(3), e)(1).

b) Applicable Emissions Limitations and/or Control Requirements

(1) The specific operations(s), property, and/or equipment that constitute each emissions unit along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from each unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3)	Emissions of Particulate Matter 10 microns or less in diameter (PM10) shall not exceed 0.005 lb/hour and 0.02 ton per year. See b)(2)b. The requirements for this rule also include compliance with the requirements of OAC rule 3745-31-05(D).
b.	OAC rule 3745-31-05(D) Synthetic minor to avoid non-attainment new source review and Title V permitting	OC emissions shall not exceed 1.0 ton per year (TPY) as a rolling 12 month summation. See c)(2)
c.	OAC rule 3745-17-07, OAC 3745-17-08	The emission limitation specified by this rule is less stringent than the emission limitations established pursuant to OAC rule 3745-31-05 (A)(3) for PM10 and OAC rule 3745-17-11 for PE.
d.	OAC rule 3745-17-11	Particulate Emissions (PE) shall not exceed 2.0 lbs/hr.

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
e.	OAC rule 3745-31-05(E)	See c)(1)
f.	OAC rule 3745-21-07 (G)	The OC emission limitation specified by this rule is less stringent than the emission limitations pursuant to OAC 3745-31-05(D) and OAC 3745-31-05(E).
g.	ORC 3704.03(F)(4)(b)	See g)(1)

(2) Additional Terms and Conditions

a. Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of HEPA filter, material usage limitation, an operating hours limitation and compliance with the visible and mass emissions limitations.

b. The Best Available Technology (BAT) requirements under OAC rule 3745-31-05(A)(3) do not apply to the particulate emissions from this air contaminant source since the calculated annual emission rate for particulate emissions is less than ten tons per year taking into account the federally enforceable rule limitation of 2.0 lbs/hr as derived from OAC 3745-17-11.The uncontrolled potential to emit particulate matter emissions less than 10 microns or less in diameter (PM10) from this air contaminant source is over 10 tons per year and therefore pursuant to SB265 this air contaminant source is subject to OAC rule 3745-31-05(A)(3) for PM10.

c. The requirements established under OAC rule 3745-21-07 shall cease to be effective and federally enforceable on the date the U.S. EPA approves the current rule as a revision to the Ohio SIP for the control of organic compounds.

c) Operational Restrictions

(1) The organic liquids usage rate in this in this emissions unit shall not exceed 5.1 pounds per hour.

(2) The spraying of organic liquids in this emission unit shall not exceed 79 hours per year, as a rolling, 12-month summation. The permittee has records to demonstrate compliance with this limitation upon issuance of this permit..

d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall collect and record the following information each day for each batch using organic liquids:

a. Date the batch was produced.

b. The total OC usage (amount of organic liquids used) in pounds per batch.

c. The duration of the spraying time of the batch, in hours.

d. The hourly OC usage rate (b./c.).

(2) The permittee shall collect and record the following information each month for this emissions unit:

a. The duration of the spraying time of the batch, in hours.

b. The monthly OC emissions calculated as follows:

Monthly OC emissions (lbs/month) = total solvent sprayed during a month (pounds)

c. The updated rolling, 12-month summation of the hours spraying organic liquids. This shall include the information for the current month and the preceding eleven calender months.

d. The updated rolling, 12-month summation of the OC emissions. This shall include the information for the current month and the preceding eleven calender months.

(3) The permittee shall collect and record the following information each month:

a. the company identification of each liquid organic material employed in this emissions unit; and

b. a record of each liquid organic material employed in this emissions unit indicating, whether or not the liquid organic material is photochemically reactive as identified in OAC rule 3745-21-01 (C)(5).

e) Reporting Requirements

(1) The permittee shall submit deviation (excursion) reports that identify all exceedances of the following:

a. Each hour during which the organic liquids usage amount exceeded 25.1 lbs/hour, and the actual organic liquids usage amount for each such hour.

b. The permittee shall notify the Hamilton County Department of Environmental Services of any exceedance of the rolling, 12-month hours of operation limitation set forth in c)(2) and the rolling, 12-month OC emissions limitation set forth in b)(1). The reports shall be submitted to the Director (the Hamilton County Department of Environmental Services) by January 31, April 30, July 31 and October 31 of each year and shall cover the previous three calendar months (October through December, January through March, April through June and July through September, respectively.)

If no exceedances occurred, the permittee shall state so in the report.

(2) The permitte shall notify the Hamilton County Department of Environmental Services in writing identifying each day during which any photochemically reactive material (as defined in OAC rule 3745-21-01 (C)(5) was employed in this emissions unit. This report shall identify the cause for the use of the photochemically reactive material(s) and the estimated total quantity of organic compound emissions emitted each such day. This

report shall be submitted to the Hamilton County Department of Environmental Services within 45 days after the exceedance occurs.

(3) Annual Permit Evaluation Report (PER) forms will be mailed to the permittee at the end of the reporting period specified in the Authorization section of this permit. The permittee shall submit the PER in the form and manner provided by the director by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting period of no more than twelve-months for each air contaminant source identified in this permit.

f) Testing Requirements

(1) Compliance with the emission limitations specified in Section b)(1) shall be determined by the following methods:

a. Emissions limitation:

Visible particulate emissions from any stack shall not exceed 20 percent opacity as a six-minute average, except as specified by rule.

Applicable Compliance Method:

Compliance shall be determined through visible emission observations performed in accordance with 40 CFR Part 60, Appendix A, Method 9 and the procedures specified in OAC rule 3745-17-03(B)(1).

b. Emissions limitations:

0.005 lb/hour and 0.02 ton per year of PM10.

Applicable Compliance Method:

Compliance shall be determined utilizing the total dry material maximum throughput (662.2 lbs/hr) multiplied by the maximum loss factor (0.025) times 1 minus the minimum HEPA control efficiency of 99.97%, as provided in permit to install application 14-05839 received on April 28, 2006. The annual emission rate shall be determined by multiplying the hourly emission rate by 8760 hours per year and dividing by 2000 lbs/ton.

c. Emissions limitation:

2.0 lbs of PE/hour.

Applicable Compliance Method:

Compliance may be demonstrated by utilizing Table I from OAC rule 3745-17-11 employing the total dry material maximum throughput of 0.3311 ton /hr) as P in Table I .

If required, compliance shall be demonstrated by employing methods 1-5 of 40 CFR Part 60, Appendix A.

d. Emissions limitation:

1.0 ton per year of OC based upon a rolling 12-month summation of the monthly OC emissions.

Applicable Compliance Method:

Compliance shall be determined by the record keeping in d)(2).

(2) Compliance with the organic liquid usage limitation in c)(1) shall be demonstrated by the record keeping in term and condition d)(1).

(3) Compliance with the organic liquid spraying limitation in c)(2) shall be demonstrated by the record keeping in d)(2).

(4) Formulation data or USEPA method 24 or 24A shall be used to determine the OC contents of the organic liquids.

g) Miscellaneous Requirements

(1) Modeling to demonstrate compliance with the Ohio EPA=s AAir Toxic Policy@ was not necessary because the emissions unit=s maximum annual emissions for each toxic pollutant will be less than 1.0 ton. OAC Chapter 3745-31 requires a permittee to apply for and obtain a new or modified permit to install prior to making a Amodification@ as defined by OAC rule 3745-31-01. The permittee is hereby advised that a new permit to install application would be required for an emissions unit if changes in the composition of the materials or use of new materials would cause the emissions of any pollutant that has a listed Threshold Limit Value (TLV), as documented in the most current version of the American Conference of Governmental Industrial Hygienists= (ACGIH=s) handbook entitled ATLVs and BEIs@ (AThreshold Limit Values for Chemical Substances and Physical Agents, Biological Exposure Indices@), to increase to above 1.0 ton per year.