



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL
BUTLER 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: 14-05819

Fac ID: 1409040987

DATE: 4/20/2006

Amylin Ohio, L.L.C.
Brad Stanard
9360 Towne Centre Drive
San Diego, CA 92121

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
309 South Fourth Street, Room 222
Columbus, Ohio 43215

Sincerely,

Michael W. Ahern, Manager
Permit Issuance and Data Management Section
Division of Air Pollution Control

CC: USEPA

HCDES



**Permit To Install
Terms and Conditions**

**Issue Date: 4/20/2006
Effective Date: 4/20/2006**

FINAL PERMIT TO INSTALL 14-05819

Application Number: 14-05819
Facility ID: 1409040987
Permit Fee: **\$400**
Name of Facility: Amylin Ohio, L.L.C.
Person to Contact: Brad Stanard
Address: 9360 Towne Centre Drive
San Diego, CA 92121

Location of proposed air contaminant source(s) [emissions unit(s)]:
**8814 Tradeport Drive
Hamilton, Ohio**

Description of proposed emissions unit(s):
Installation of Exanatide Microspheres Production Line.

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

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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

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

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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)

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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 cannot meet the requirements of this permit 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 cannot meet the requirements of this permit 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 Permit To Install for the installation or modification of any other emissions unit(s) are required for any emissions unit for which a Permit To Install is required.

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.

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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 ninety (90) days after commencing operation of the emissions unit(s) covered by this permit.

14. 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.

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

Pollutant

Tons Per Year

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PE/PM10	3.3
OC	13.12
SO2	31.94
NOx	8.95
CO	5.16

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>
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B001 - 14.3 mmBtu/hr dual fuel Cleaver Brooks Boiler No. 3	OAC rule 3745-31-05(A)(3)
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OAC rule 3745-17-07(A)(1)

OAC rule 3745-17-10(B)(1)

OAC rule 3745-18-06(D)

Emissions Unit ID: B001

OAC rule 3745-21-08(B)

OAC rule 3745-23-06(B)

40 CFR Part 60 Subpart Dc

Applicable Emissions
Limitations/Control Measures

Particulate emissions (PE) shall not exceed 0.014 lb/mmBtu and 0.89 ton per year (TPY).

Particulate Matter emissions ten microns and less in diameter (PM10) shall not exceed 0.008 lb/mmBtu and 0.49 ton per year (TPY).

Sulfur dioxide (SO2) emissions shall not exceed 0.51 lb/mmBtu and 31.94 TPY.

Nitrogen oxides (NOx) emissions shall not exceed 0.14 lb/mmBtu and 8.95 TPY.

Carbon Monoxide (CO) emissions shall not exceed 0.082 lb/mmBtu and 5.16 TPY.

Organic Compound (OC) emissions shall not exceed 0.011 lb/mmBtu and 0.68 TPY.

Visible particulate emissions from any stack shall not exceed 10% opacity, as a six minute average, except for one 6-minute period per hour of not more than 27% opacity.

See terms and conditions B.1 and B.2.

The requirements of this rule

also include compliance with the requirements of OAC rule 3745-21-08(B), OAC rule OAC rule 3745-23-06(B) and 40CFR60 Subpart Dc.

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

When burning No. 2 fuel oil, the emissions limitation specified by this rule is less stringent than the emissions limitation pursuant to OAC rule 3745-31-05(A)(3).

See term A.2.d.

See term A.2.e.

See term A.2.b.

2. Additional Terms and Conditions

- 2.a** Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the use of natural gas or No. 2 fuel oil, a sulfur content limitation for No. 2 fuel oil, and the emissions limitations listed in term A.1 above.
- 2.b** The application and enforcement of the provisions of the New Source Performance Standards (NSPS), as promulgated by the United States Environmental Protection Agency (U.S. EPA), 40 CFR Part 60, are delegated to the Ohio Environmental Protection Agency (Ohio EPA).
- 2.c** The lb/mmBtu actual heat input and tons per year emission limitations are based on the emissions unit's potentials to emit. Therefore, no monitoring, record keeping, and reporting requirements are necessary to ensure ongoing compliance with these emission limitations.
- 2.d** The permittee has satisfied the "best available control techniques and operating practices" required pursuant to OAC rule 3745-21-08(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3).

On November 5, 2002, OAC rule 3745-21-08 was revised to delete paragraph (B); therefore, paragraph (B) is no longer part of the State regulations. However, that rule revision has not yet been submitted to U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revisions occurs and the U.S. EPA approves the revisions to OAC rule 3745-21-08, the requirement to satisfy the "best available control techniques and operating practices" still exists as part of the federally-approved SIP for Ohio.

- 2.e** The permittee has satisfied the "latest available control techniques and operating practices" required pursuant to OAC rule 3745-23-06(B) by committing to comply with the best available technology requirements established pursuant to OAC rule 3745-31-05(A)(3).

On February 15, 2005, OAC rule 3745-23-06 was rescinded and therefore no longer a part of State regulations. However, that rule revision has not yet been submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-23-06, the requirement to satisfy "latest available

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Emissions Unit ID: B001

control techniques and operational practices" still exists as part of the federally-approved SIP for Ohio.

B. Operational Restrictions

1. The permittee shall burn only natural gas and/or No. 2 fuel oil in this emissions unit.
2. The quality of No. 2 fuel oil received for burning in this emissions unit shall have a combination of sulfur content and heat content sufficient to comply with the allowable sulfur dioxide emission limitation of 0.51 lb/mmBtu of actual heat input and the sulfur content limitation for No. 2 fuel oil of less than or equal to 0.5 weight percent sulfur.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall maintain records of the oil burned in this emissions unit in accordance with either Alternative 1 or Alternative 2 described below.

Alternative 1:

For each shipment of oil received for burning in this emissions unit, the permittee shall collect or require the oil supplier to collect a representative grab sample of oil and maintain records of the total quantity of oil received, the permittee's or oil supplier's analyses for sulfur content and heat content, and the calculated sulfur dioxide emission rate (in lb/mmBtu). [The sulfur dioxide emission rate shall be calculated in accordance with the formula specified in OAC rule 3745-18-04(F)]. A shipment may be comprised of multiple tank truck loads from the same supplier's batch, and the quality of the oil for those loads may be represented by a single batch analysis from the supplier.

Alternative 2:

The permittee shall collect a representative grab sample of oil that is burned in this emissions unit for each day when the emissions unit is in operation. If additional fuel oil is added to the tank serving this emissions unit on a day when the emissions unit is in operation, the permittee shall collect a sufficient number of grab samples to develop a composite sample representative of the fuel oil burned in this emissions unit. A representative grab sample of oil does not need to be collected on days when this emissions unit is only operated for the purpose of "test-firing." The permittee shall maintain records of the total quantity of oil burned each day, except for the purpose of test-firing, the permittee's analyses for sulfur content and heat content, and the calculated sulfur dioxide emission rate (in lb/mmBtu). [The sulfur dioxide emission rate shall be calculated in accordance with the formula specified in OAC rule 3745-18-04(F)].

The permittee shall perform or require the supplier to perform the analyses for sulfur content and heat content in accordance with 40 CFR Part 60, Appendix A, Method 19, or the appropriate ASTM methods (such as, ASTM methods D240 and D4294), or equivalent methods as approved by the Director.

2. The owner or operator of each affected facility shall record and maintain records of the amounts of each fuel combusted during each day.
3. The permittee shall maintain monthly records of the following information:
 - a. The total volume of natural gas (mmft³) burned in this emissions unit.

- b. The total number of gallons of No. 2 fuel oil used in this boiler for each month.

D. Reporting Requirements

1. Pursuant to the NSPS, the permittee is required to report the following information at the appropriate times (if the information has not already been reported):
 - a. construction date (no later than 30 days after such date);
 - b. anticipated start-up date (not more than 60 days or less than 30 days prior to such date);
 - c. actual start-up date (within 15 days after such date); and,
 - d. date of performance testing (if required, at least 30 days prior to testing).

Reports are to be sent to the appropriate local air agency or District Office and to:

Ohio Environmental Protection Agency
DAPC - Permit Management Unit
P.O. Box 163669
Columbus, Ohio 43216-3669

2. The permittee shall notify the Hamilton County Department of Environmental Services in writing of any fuel burned in this emissions unit other than natural gas or No. 2 fuel oil.
3. The permittee shall notify the Hamilton County Department of Environmental Services in writing of any record which shows a deviation of the allowable sulfur dioxide emission limitation and/or sulfur content limitation based upon the record keeping requirements from term C.1. above.
4. The notifications identified in terms D.2 and D.3 shall include a copy of such record and shall be sent to the Hamilton County Department of Environmental Services within 45 days after the deviation occurs.

E. Testing Requirements

1. Compliance with the emission limitations in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:

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Emissions Unit ID: B001

- a. Emissions Limitation:
10% opacity, as a six-minute average, except for one 6-minute period per hour of not more than 27% opacity.

Applicable Compliance Method:

If required, compliance shall be determined through visible emission observations performed in accordance with U.S. EPA Reference Method 9 in 40 CFR, Part 60, Appendix A.

- b. Emissions Limitations:
0.14 lb/mmBtu, 8.95 TPY NO_x

Applicable Compliance Method:

The emissions limitations were based upon the emissions factor from AP-42, "Compilation of Air Pollutant Emission Factors", 5th Edition, Section 1.3, Table 1.3-1 (9/98). Compliance with the lb/mmBtu emissions limitation may be determined by converting the 20 lbs NO_x/10³ gal emissions factor into lb NO_x/mmBtu by dividing by 140 mmBtu/10³ gal. Compliance with the annual emission limitation may be demonstrated by multiplying the lb NO_x/mmBtu value by the maximum rated heat input capacity of the emissions unit (in mmBtu/hr), then multiplying by 8760 hrs/yr and dividing by 2000 lbs/ton.

If required, the permittee shall demonstrate compliance with the lb/mmBtu emissions limitation through emission tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1- 4, and 7.

- c. Emissions Limitations:
0.082 lb/mmBtu, 5.16 TPY CO

Applicable Compliance Method:

The emissions limitations were based upon the emission factor from AP-42, "Compilation of Air Pollutant Emission Factors", 5th Edition, Section 1.4, Table 1.4-1 (7/98). Compliance with the lb/mmBtu emission limitation may be determined by converting the 84 lbs CO/10⁶ scf emission factor into lb CO/mmBtu by dividing by 1,020 Btu/scf. Compliance with the annual emission limitation may be demonstrated by multiplying the lb CO/mmBtu value by the maximum rated heat input capacity of the emissions unit (in mmBtu/hr), then multiplying by 8760 hrs/yr and dividing by 2000 lbs/ton.

If required, the permittee shall demonstrate compliance with the lb/mmBtu emissions limitation through emissions tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1- 4, and 10.

- d. Emissions Limitations:
0.011 lb/mmBtu, 0.68 TPY OC

Applicable Compliance Method:

The emission limitations were based upon the emission factor from AP-42, "Compilation of Air Pollutant Emission Factors", 5th Edition, Section 1.4, Table 1.4-2 (7/98). Compliance with the lb/mmBtu emission limitation may be determined by converting the 11 lbs TOC/10⁶ scf emission factor into lb

TOC/mmBtu by dividing by 1,020 Btu/scf. Compliance with the annual emission limitation may be demonstrated by multiplying the lb TOC/mmBtu value by the maximum rated heat input capacity of the emissions unit (in mmBtu/hr), then multiplying by 8760 hrs/yr and dividing by 2000 lbs/ton.

If required, the permittee shall demonstrate compliance with the lb/mmBtu emissions limitation through emissions tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1- 4, and 25.

- e. Emissions Limitations:
0.51 lb/mmBtu, 31.94 TPY SO₂

Applicable Compliance Method:

The emissions limitations were based upon the emission factor from AP-42, "Compilation of Air Pollutant Emission Factors", 5th Edition, Section 1.3, Table 1.3-1 (9/98). Compliance with the lb/mmBtu emissions limitation shall be based upon the record keeping in term C.1 and shall be determined in accordance with the following formula, as specified in OAC rule 3745-18-04(F):

$ER = (1 \times 10^6) / H \times D \times S \times 1.974$, where:

ER = the emissions rate in pounds SO₂/mmBtu;

H = the heat content of the No. 2 fuel oil in Btu/gallon;

D = the density of the No. 2 fuel oil in lb/gallon; and

S = the decimal fraction of sulfur in the No. 2 fuel oil.

Compliance with the annual emissions limitation shall be determined by multiplying the annual average lb SO₂/mmBtu value by the annual average heat content and the total gallons of No. 2 fuel oil burned, and then dividing by 2000 lbs/ton.

If required, the permittee shall demonstrate compliance with the lb/mmBtu emissions limitation through emissions tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1- 4, and 6.

- f. Emissions Limitations:
0.014 lb/mmBtu, 0.89 TPY PE

Applicable Compliance Method:

The emissions limitations were based upon the emission factor from AP-42, "Compilation of Air Pollutant Emission Factors", 5th Edition, Section 1.3, Table

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1.3-1 (9/98). Compliance with the lb/mmBtu emission limitation may be determined by converting the 2 lbs PE/10³ gal emission factor into lbs PE/mmBtu by dividing by 140 mmBtu/10³ gal. Compliance with the annual emission limitation may be demonstrated by multiplying the lb PE/mmBtu value by the maximum rated heat input capacity of the emissions unit (in mmBtu/hr), then multiplying by 8760 hrs/yr and dividing by 2000 lbs/ton.

If required, the permittee shall demonstrate compliance with the lb/mmBtu emissions limitation through emissions tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1- 5.

- g. Emissions Limitations:
0.008 lb/mmBtu, 0.49 TPY PM10

Applicable Compliance Method:

The emissions limitations were based upon the emission factor from AP-42, "Compilation of Air Pollutant Emission Factors", 5th Edition, Section 1.3, Table 1.3-7 (9/98). Compliance with the lb/mmBtu emission limitation may be determined by converting the 1.1 lbs PM10/10³ gal emission factor into lbs PM10/mmBtu by dividing by 140 mmBtu/10³ gal. Compliance with the annual emissions limitation may be demonstrated by multiplying the lb PM10/mmBtu value by the maximum rated heat input capacity of the emissions unit (in mmBtu/hr), then multiplying by 8760 hrs/yr and dividing by 2000 lbs/ton.

- h. Sulfur Content Limitation:
≤ 0.5 weight percent sulfur in the No. 2 fuel oil

Applicable Compliance Method:

Compliance shall be demonstrated by the record keeping requirement described in term C.1.

F. Miscellaneous Requirements

None

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>	OAC rule 3745-17-11(B)
P001 - Microspheres production line No. 1	OAC rule 3745-31-05(A)(3)	
	OAC rule 3745-17-07(A)(1)	

Applicable Emissions
Limitations/Control Measures

Particulate Matter emissions ten microns and less in diameter (PM10) shall not exceed 0.55 lb per hour; and Particulate emissions (PE) and PM10 shall not exceed 2.41 tons per year (TPY).

Visible particulate emissions from any stack shall not exceed 10 percent opacity, as a six-minute average.

The requirements of this rule also include compliance with the requirements of OAC rule 3745-17-11.

Volatile organic compound (VOC) emissions shall not exceed 2.84 lbs per hour and 12.44 TPY.

The emissions limitation specified by this rule is less stringent than the emissions limitation established pursuant to OAC rule 3745-31-05(A)(3).

Particulate emissions (PE) shall not exceed 0.55 lb per hour.

2. Additional Terms and Conditions

2.a The pounds per hour and tons per year emissions limitations specified in Section

Emissions Unit ID: P001

A. are based upon the emissions unit's Potential to Emit (PTE). Therefore, no records are required to demonstrate compliance with these emissions limitations.

- 2.b Compliance with OAC rule 3745-31-05(A)(3) shall be demonstrated by the visible emissions limitation and the mass emissions limitations.

B. Operational Restrictions

None

C. Monitoring and/or Recordkeeping Requirements

1. The permit to install for this emissions unit P001 was evaluated based on the actual materials and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied to this emissions unit for each toxic pollutant, using data from the permit to install application, and modeling was performed for the toxic pollutant(s) emitted at over a ton per year using the SCREEN3 model or other Ohio EPA approved model. The predicted 1-hour maximum ground-level concentration result(s) from the use of the SCREEN3 (or other approved) model, was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC), calculated as required in Engineering Guide #70. The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: methylene chloride

TLV (ug/m3): 173,681

Maximum Hourly Emission Rate (lbs/hr): 7.33

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 498

MAGLC (ug/m3): 4135

Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:

- a. changes in the composition of the materials used or the use of new materials,

that would result in the emission of a compound or chemical with a lower Threshold Limit Value (TLV) than the lowest TLV previously modeled, as documented in the most current version of the American Conference of Governmental Industrial Hygienists' (ACGIH's) handbook entitled "TLVs and BEIs" ("Threshold Limit Values for Chemical Substances and Physical Agents, Biological Exposure Indices");

- b. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and
- c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) meet(s) the definition of a "modification" under other provisions of the rule, then the permittee shall obtain a final permit to install prior to the change.

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

- a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);
- b. documentation of the evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and
- c. where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

Amylin Ohio, L.L.C.
PTI Application: 14-05910
Issue:

Facility ID: 1409040987

Emissions Unit ID: P001

None

E. Testing Requirements

1. Compliance with the emissions limitations in Section A.1 of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emissions Limitations:
0.55 pound per hour and 2.41 TPY PE/PM10

Applicable Compliance Method:

The hourly emissions limitation of 0.55 pound per hour was set based on Table I in OAC rule 3745-17-11 and a process weight rate of less than 0.05 ton/hr for the process.

If required, the permittee shall demonstrate compliance with the lb/hr PE limitation through emission tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1 through 5.

Compliance with the annual PE limitation shall be determined by multiplying the maximum hourly PE by the maximum hours of operation and converting to TPY by multiplying by 1 ton/2000 lb.

All PE was assumed to be PM10.

- b. **Emissions Limitations:**
2.84 pounds per hour and 12.44 TPY VOC

Applicable Compliance Method:

Compliance with the hourly emissions limitation shall be demonstrated by the VOC emissions calculation methodology documented in permit to install application 14-05819, received on February 28, 2006.

If required, the permittee shall demonstrate compliance with the lb/hr VOC emissions limitation through emission tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1 through 4 and 25 or 25a.

Compliance with the annual VOC emissions limitation shall be determined by multiplying the maximum hourly VOC emissions by the maximum hours of operation (hr/yr) and converting to TPY by multiplying by 1 ton/2000 lb.

- c. **Emissions Limitation:**
Visible particulate emissions from any stack shall not exceed 10% opacity, as a 6-minute average.

Applicable Compliance Method:

If required, compliance shall be determined through visible emissions

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PTI A

Issued: 4/20/2006

Emissions Unit ID: **P001**

observations performed in accordance with 40 CFR Part 60, Appendix A, Method 9.

F. Miscellaneous Requirements

None