John R. Kasich, Governor
Mary Taylor, Lt. Governor
Scott J. Nally, Director

7/26/2013

Certified Mail

Patrick Stenski
Amylin Ohio LLC
8814 Trade Port Drive
West Chester, OH 45071

No	TOXIC REVIEW
No	PSD
No	SYNTHETIC MINOR TO AVOID MAJOR NSR
No	CEMS
Yes	MACT/GACT
No	NSPS
No	NESHAPS
No	NETTING
No	MAJOR NON-ATTAINMENT
No	MODELING SUBMITTED
No	MAJOR GHG
No	SYNTHETIC MINOR TO AVOID MAJOR GHG

RE: FINALAIR POLLUTION PERMIT-TO-INSTALL
Facility ID: 1409040987
Permit Number: P0114889
Permit Type: OAC Chapter 3745-31 Modification
County: Butler

Dear Permit Holder:

Enclosed please find a final Ohio Environmental Protection Agency (EPA)Air Pollution Permit-to-Install (PTI) which will allow you to install or modify the described emissions unit(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, we urge you to read it carefully. Because this permit contains conditions and restrictions, please read it very carefully. In this letter you will find the information on the following topics:

- **How to appeal this permit**
- **How to save money, reduce pollution and reduce energy consumption**
- **How to give us feedback on your permitting experience**
- **How to get an electronic copy of your permit**

How to appeal this permit

The issuance of this PTI is a final action of the Director and may be appealed to the Environmental Review Appeals Commission pursuant to Section 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. The appeal must be filed with the Commission within thirty (30) days after notice of the Director's action. The appeal must be accompanied by a filing fee of $70.00, made payable to “Ohio Treasurer Josh Mandel," which the Commission, in its discretion, may reduce if by affidavit you demonstrate that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3) days of filing with the Commission. Ohio EPA requests that a copy of the appeal be served upon the Ohio Attorney General’s Office, Environmental Enforcement Section. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
77 South High Street, 17th Floor
Columbus, OH 43215

How to save money, reduce pollution and reduce energy consumption

The Ohio EPA is encouraging 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 Compliance Assistance and Pollution Prevention at (614) 644-3469. Additionally, all or a portion of the capital expenditures related to installing air pollution control equipment under this permit may be eligible for financing and State tax exemptions through the Ohio Air Quality Development Authority (OAQDA) under Ohio Revised Code Section 3706. For more information, see the OAQDA website: www.ohioairquality.org/clean_air

How to give us feedback on your permitting experience

Please complete a survey at www.epa.ohio.gov/dapc/permitsurvey.aspx and give us feedback on your permitting experience. We value your opinion.

How to get an electronic copy of your permit

This permit can be accessed electronically via the eBusiness Center: Air Services in Microsoft Word format or in Adobe PDF on the Division of Air Pollution Control (DAPC) Web page, www.epa.ohio.gov/dapc by clicking the "Search for Permits" link under the Permitting topic on the Programs tab.

If you have any questions, please contact Southwest Ohio Air Quality Agency at (513)946-7777 or the Office of Compliance Assistance and Pollution Prevention at (614) 644-3469.

Sincerely,

Michael W. Ahern

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

Cc: U.S. EPA
SWOAQA; Indiana; Kentucky

FINAL

Division of Air Pollution Control
Permit-to-Install
for
Amylin Ohio LLC

Facility ID:	1409040987
Permit Number:	P0114889
Permit Type:	OAC Chapter 3745-31 Modification
Issued:	7/26/2013
Effective:	7/26/2013

Division of Air Pollution Control
Permit-to-Install
for
Amylin Ohio LLC

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Authorization

Facility ID:	1409040987
Facility Description:	Pharmaceuticals manufacturer
Application Number(s):	A0047995
Permit Number:	P0114889
Permit Description:	Chapter 31 modification for Pharmaceutical Production Line 1.
Permit Type:	OAC Chapter 3745-31 Modification
Permit Fee:	$200.00
Issue Date:	7/26/2013
Effective Date:	7/26/2013

This document constitutes issuance to:

Amylin Ohio LLC
8814 Trade Port Drive
West Chester Twp., OH 45071

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

Ohio Environmental Protection Agency (EPA) District Office or local air agency responsible for processing and administering your permit:

Southwest Ohio Air Quality Agency
250 William Howard Taft Rd.
Cincinnati, OH 45219
(513)946-7777

The above named entity is hereby granted a Permit-to-Install for the 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 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

Scott J. Nally
Director

Authorization (continued)

Permit Number: P0114889
Permit Description: Chapter 31 modification for Pharmaceutical Production Line 1.

Permits for the following Emissions Unit(s) or groups of Emissions Units are in this document as indicated below:

Emissions Unit ID:	**P001**
Company Equipment ID:	Production Line No. 1
Superseded Permit Number:	14-05957
General Permit Category and Type:	Not Applicable

A. Standard Terms and Conditions

1. Federally Enforceable Standard Terms and Conditions

a) All Standard Terms and Conditions are federally enforceable, with the exception of those listed below which are enforceable under State law only:

(1) Standard Term and Condition A.2.a), Severability Clause

(2) Standard Term and Condition A.3.c) through A. 3.e)General Requirements

(3) Standard Term and Condition A.6.c) and A. 6.d), Compliance Requirements

(4) Standard Term and Condition A.9., Reporting Requirements

(5) Standard Term and Condition A.10., Applicability

(6) Standard Term and Condition A.11.b) through A.11.e), Construction of New Source(s) and Authorization to Install

(7) Standard Term and Condition A.14., Public Disclosure

(8) Standard Term and Condition A.15., Additional Reporting Requirements When There Are No Deviations of Federally Enforceable Emission Limitations, Operational Restrictions, or Control Device Operating Parameter Limitations

(9) Standard Term and Condition A.16., Fees

(10) Standard Term and Condition A.17., Permit Transfers

2. Severability Clause

a) A determination that any term or condition of this permit is invalid shall not invalidate the force or effect of any other term or condition thereof, except to the extent that any other term or condition depends in whole or in part for its operation or implementation upon the term or condition declared invalid.

b) All terms and conditions designated in parts B and C of this permit are federally enforceable as a practical matter, if they are required under the Act, or any of its applicable requirements, including relevant provisions designed to limit the potential to emit of a source, are enforceable by the Administrator of the U.S. EPA and the State and by citizens (to the extent allowed by section 304 of the Act) under the Act. Terms and conditions in parts B and C of this permit shall not be federally enforceable and shall be enforceable under State law only, only if specifically identified in this permit as such.

3. General Requirements

a) The permittee must comply with all terms and conditions of this permit. Any noncompliance with the federally enforceable terms and conditions of this permit constitutes a violation of the Act, and is grounds for enforcement action or for permit revocation, revocation and re-issuance, or modification.

b) It shall not be a defense for the permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the federally enforceable terms and conditions of this permit.

c) This permit may be modified, revoked, or revoked and reissued, for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or revocation, or of a notification of planned changes or anticipated noncompliance does not stay any term and condition of this permit.

d) This permit does not convey any property rights of any sort, or any exclusive privilege.

e) 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 or revoking this permit or to determine compliance with this permit. Upon request, the permittee shall also furnish to the Director or an authorized representative of the Director, copies of records required to be kept by this permit. For information claimed to be confidential in the submittal to the Director, if the Administrator of the U.S. EPA requests such information, the permittee may furnish such records directly to the Administrator along with a claim of confidentiality.

4. Monitoring and Related Record Keeping and Reporting Requirements

a) Except as may otherwise be provided in the terms and conditions for a specific emissions unit, the permittee shall maintain records that include the following, where applicable, for any required monitoring under this permit:

(1) The date, place (as defined in the permit), and time of sampling or measurements.

(2) The date(s) analyses were performed.

(3) The company or entity that performed the analyses.

(4) The analytical techniques or methods used.

(5) The results of such analyses.

(6) The operating conditions existing at the time of sampling or measurement.

b) 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.

c) Except as may otherwise be provided in the terms and conditions for a specific emissions unit, the permittee shall submit required reports in the following manner:

(1) Reports of any required monitoring and/or recordkeeping of federally enforceable information shall be submitted to the Southwest Ohio Air Quality Agency.

(2) Quarterly written reports of (i) any deviations from federally enforceable emissionlimitations, operationalrestrictions, andcontroldeviceoperatingparameterlimitations, excluding deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06, that have been detected by the testing, monitoring and recordkeeping requirements specified in this permit, (ii) the probable cause of such deviations, and (iii) any corrective actions or preventive measures taken, shall be made to the Southwest Ohio Air Quality Agency. The written reports shall be submitted (i.e., postmarked) quarterly, by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. See A.15. below if no deviations occurred during the quarter.

(3) Written reports, which identify any deviations from the federally enforceable monitoring, recordkeeping, andreportingrequirements contained in this permit shall be submitted (i.e., postmarked) to the Southwest Ohio Air Quality Agency every six months, by January 31 and July 31 of each year for the previous six calendar months. If no deviations occurred during a six-month period, the permittee shall submit a semi-annual report, which states that no deviations occurred during that period.

(4) This permit is for an emissions unit located at a Title V facility. Each written report shall be signed by a responsible official certifying that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

d) The permittee shall report actual emissions pursuant to OAC Chapter 3745-78 for the purpose of collecting Air Pollution Control Fees.

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, i.e., upset, of any emissions units or any associated air pollution control system(s) shall be reported to the Southwest Ohio Air Quality Agency in accordance with paragraph (B) of OAC rule 3745-15-06. (The definition of an upset condition shall be the same as that used in OAC rule 3745-15-06(B)(1) for a malfunction.) The verbal and written reports shall be submitted pursuant to 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 emission unit(s) that is (are) served by such control system(s).

6. Compliance Requirements

a) The emissions unit(s) identified in this Permit shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

b) Any document (including reports) required to be submitted and required by a federally applicable requirement in this permit shall include a certification by a responsible official that, based on information and belief formed after reasonable inquiry, the statements in the document are true, accurate, and complete.

c) Upon presentation of credentials and other documents as may be required by law, the permittee shall allow the Director of the Ohio EPA or an authorized representative of the Director to:

(1) At reasonable times, enter upon the permittee's premises where a source is located or the emissions-related activity is conducted, or where records must be kept under the conditions of this permit.

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit, subject to the protection from disclosure to the public of confidential information consistent with ORC section 3704.08.

(3) Inspect at reasonable times any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit.

(4) As authorized by the Act, sample or monitor at reasonable times substances or parameters for the purpose of assuring compliance with the permit and applicable requirements.

d) The permittee shall submit progress reports to the Southwest Ohio Air Quality Agency concerning any schedule of compliance for meeting an applicable requirement. Progress reports shall be submitted semiannually or more frequently if specified in the applicable requirement or by the Director of the Ohio EPA. Progress reports shall contain the following:

(1) Dates for achieving the activities, milestones, or compliance required in any schedule of compliance, and dates when such activities, milestones, or compliance were achieved.

(2) An explanation of why any dates in any schedule of compliance were not or will not be met, and any preventive or corrective measures adopted.

7. Best Available Technology

As specified in OAC Rule 3745-31-05, new sources that must employ Best Available Technology (BAT) shall comply with the Applicable Emission Limitations/Control Measures identified as BAT for each subject emissions unit.

8. 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.

9. Reporting Requirements

The permittee shall submit required reports in the following manner:

a) Reports of any required monitoring and/or recordkeeping of state-only enforceable information shall be submitted to the Southwest Ohio Air Quality 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 state-only required 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 Southwest Ohio Air Quality 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 (i.e., postmarked) quarterly, 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.)

10. 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).

11. Construction of New Sources(s) and Authorization to Install

a) This permit does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. This permit does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the application and terms and conditions of this permit. 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 this permit does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Issuance of this permit 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.

b) If applicable, authorization to install any new emissions unit included in this permit shall terminate within eighteen months of the effective date of the permit if the owner or operator has not undertaken a continuing program of installation or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation. 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.

c) The permittee may notify Ohio EPA of any emissions unit that is permanently shut down (i.e., 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) by submitting a certification from the authorized official that identifies the date on which the emissions unit was permanently shut down. Authorization to operate the affected emissions unit shall cease upon the date certified by the authorized official that the emissions unit was permanently shut down. At a minimum, notification of permanent shut down shall be made or confirmed by marking the affected emissions unit(s) as “permanently shut down” in Ohio EPA’s “Air Services” along with the date the emissions unit(s) was permanently removed and/or disabled. Submitting the facility profile update will constitute notifying of the permanent shutdown of the affected emissions unit(s).

d) The provisions of this permit shall cease to be enforceable for each affected emissions unit after the date on which an emissions unit is permanently shut down (i.e., 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). All records relating to any permanently shutdown emissions unit, generated while the emissions unit was in operation, must be maintained in accordance with law. All reports required by this permit must be submitted for any period an affected emissions unit operated prior to permanent shut down. At a minimum, the permit requirements must be evaluated as part of the reporting requirements identified in this permit covering the last period the emissions unit operated.

No emissions unit certified by the authorized official as being permanently shut down may resume operation without first applying for and obtaining a permit pursuant to OAC Chapter 3745-31.

e) The permittee shall comply with any residual requirements related to this permit, such as the requirement to submit a deviation report, air fee emission report, or other any reporting required by this permit for the period the operating provisions of this permit were enforceable, or as required by regulation or law. All reports shall be submitted in a form and manner prescribed by the Director. All records relating to this permit must be maintained in accordance with law.

12. Permit-To-Operate Application

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).

13. Construction Compliance Certification

The applicant shall identify the following dates in the online facility profile for each new emissions unit identified in this permit.

a) Completion of initial installation date shall be enteredupon completion of construction and prior to start-up.

b) Commence operation after installation or latest modification date shall be entered within 90 days after commencing operation of the applicable emissions unit.

14. 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.

15. Additional Reporting Requirements When There Are No Deviations of Federally Enforceable Emission Limitations, Operational Restrictions, or Control Device Operating Parameter Limitations

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., postmarked), by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters.

16. 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 any permit-to-install. The permittee shall pay all applicable permit-to-operate fees within thirty days of the issuance of the invoice.

17. Permit Transfers

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The new owner must update and submit the ownership information via the “Owner/Contact Change” functionality in Air Services once the transfer is legally completed.The change must be submitted through Air Services within thirty days of the ownership transfer date.

18. Risk Management Plans

If the permittee is required to develop and register a risk management plan pursuant to section 112(r) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq. ("Act"), the permittee shall comply with the requirement to register such a plan.

19. Title IV Provisions

If the permittee is subject to the requirements of 40 CFR Part 72 concerning acid rain, the permittee shall ensure that any affected emissions unit complies with those requirements. Emissions exceeding any allowances that are lawfully held under Title IV of the Act, or any regulations adopted thereunder, are prohibited.

B. Facility-Wide Terms and Conditions

1. All the following facility-wide terms and conditions are federally enforceable with the exception of those listed below which are enforceable under state law only:

   a) None.

2. The following emissions unit contained in this permit is subject to 40 CFR Part 63, Subpart GGG: P001. The complete MACT requirements, including the MACT General Provisions may be accessed via the internet from the Electronic Code of Federal Regulations (e-CFR) website http://ecfr.gpoaccess.gov or by contacting the appropriate Ohio EPA District office or local air agency.

C. Emissions Unit Terms and Conditions

1. P001, Production Line No. 1

Operations, Property and/or Equipment Description:

Production Line No. 1

a) The following emissions unit terms and conditions are federally enforceable with the exception of those listed below which are enforceable under state law only.

(1) None.

b) Applicable Emissions Limitations and/or Control Requirements

(1) The specific operation(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 are identified below. 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), as effective 11/30/01	Particulate emissions (PE) and particulate matter emissions ten microns and less in diameter (PM10) shall not exceed 0.70 lb per hour; and 3.07 tons per year (TPY). The organic compound (OC) emissions shall not exceed 67.9 lbs per batch and 13.21 TPY. (These OC emission limitations are effective until the permittee achieves, demonstrates and maintains compliance with 40 CFR 63 Subpart GGG, which shall be no later than March 31, 2014, per Administrative Consent Order EPA-5-13-113(a)-OH-2, USEPA Region 5, July 17, 2013.) Visible particulate emissions from any stack serving this emissions unit shall not exceed 10% opacity, as a six-minute average, except as specified by rule. The OC emission limitation specified by this rule is equivalent to the emission limitation established pursuant to 40 CFR Part 63 Subpart GGG. (This OC emission limitation is effective once the permittee achieves, demonstrates and maintains compliance with 40 CFR 63 Subpart GGG, which shall be no later than March

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		31, 2014 per Administrative Consent Order EPA-5-13-113(a)-OH-2, USEPA Region 5, July 17, 2013.) See b)(2)a.
b.	OAC rule 3745-31-05(A)(3)(b), as effective 12/01/06	See b)(2)b.
c.	OAC rule 3745-31-05(A)(3)(b), as effective 12/01/06	The organic compound (OC) emissions shall not exceed 67.9 lbs per batch. (This OC emission limitation is effective until the permittee achieves, demonstrates and maintains compliance with 40 CFR 63 Subpart GGG, which shall be no later than March 31, 2014, per Administrative Consent Order EPA-5-13-113(a)-OH-2, USEPA Region 5, July 17, 2013.) The OC emission limitation specified by this rule is equivalent to the emission limitation established pursuant to 40 CFR Part 63 Subpart GGG. (This OC emission limitation is effective once the permittee achieves, demonstrates and maintains compliance with 40 CFR 63 Subpart GGG, which shall be no later than March 31, 2014 per Administrative Consent Order EPA-5-13-113(a)-OH-2, USEPA Region 5, July 17, 2013.) See b)(2)c.
d.	OAC rule 3745-17-07(A)(1)	The emission limitation specified by this rule is less stringent that the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).
e.	OAC rule 3745-17-11(B)	Particulate emissions (PE) shall not exceed 0.70 pound per hour.
f.	40 CFR Part 63 Subpart GGG (40 CFR 63.1250-1261) In accordance with 40 CFR 63.1250 this emissions unit is a pharmaceutical manufacturing process dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP.	Uncontrolled HAP emissions from the sum of all process vents within a process shall be reduced by 98 percent or greater by weight. See 40 CFR 63.1255 for equipment leak standards and 40 CFR 63.1255 for wastewater standards.

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
g.	40 CFR 63.1-63.15	Table 1 to Subpart GGG of 40 CFR Part 63 – Applicability of General Provisions to Subpart GGG which shows which parts of the General Provisions in 40 CFR Part 63 apply.
h.	Administrative Consent Order EPA-5-13-113(a)-OH-2, USEPA Region 5, July 17, 2013	See b)(2)d. and b)(2)e.

(2) Additional Terms and Conditions

a. The permittee has satisfied the Best Available Technology (BAT) requirements pursuant to Ohio Administrative Code (OAC) paragraph 3745-31-05(A)(3), as effective November 30, 2001, in this permit. On December 1, 2006, paragraph (A)(3) of OAC rule 3745-31-05 was revised to conform to the Ohio Revised Code (ORC) changes effective August 3, 2006 (Senate Bill 265 changes), such that BAT is no longer required by State regulations for National Ambient Air Quality Standards (NAAQS) pollutant(s) less than ten tons per year. However, that rule revision has not yet been approved by 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 3745-31-05, the requirement to satisfy BAT still exists as part of the federally-approved SIP for Ohio. Once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05, then these emission limitations/control measures no longer apply.

b. This rule paragraph applies once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05 as part of the State Implementation Plan.

The Best Available Technology (BAT) requirements under OAC rule 3745-31 05(A)(3) do not apply to the PE and PM10 emissions from this air contaminant source since the uncontrolled Potential to Emit (PTE) for PE and PM10 is less than 10 tons per year.

c. This rule paragraph applies once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05 as part of the State Implementation Plan.

The Best Available Technology (BAT) requirements under OAC rule 3745-31 05(A)(3) do not apply to the OC emissions from this air contaminant source since the calculated annual emission rate of OC is less than 10 tons per year taking into account the federally enforceable rule limit of 98% control under 40 CFR 63 Subpart GGG.

d. Per the Administrative Consent Order EPA-5-13-113(a)-OH-2, the permittee shall install a cryogenic condenser that reduces HAP concentrations by at least 98%on this emissions unit by February 28, 2014.

e. Per the Administrative Consent Order EPA-5-13-113(a)-OH-2, the permittee shall achieve, demonstrate and maintain compliance with 40CFR63 Subpart GGG, which shall be no later than March 31, 2014.

c) Operational Restrictions

(1) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

d) Monitoring and/or Recordkeeping Requirements

(1) Until such time as full compliance with 40CFR63 Subpart GGG is attained, the permittee shall record the production rate, the number of batches and the OC emission rate on a monthly basis.

(2) The permittee shall perform daily checks, when the emissions unit is in operation and when the weather conditions allow, for any visible particulate emissions from the stack serving this emissions unit. The presence or absence of any visible emissions shall be noted in an operations log. If visible emissions are observed, the permittee shall also note the following in the operations log:

a. the color of the emissions;

b. whether the emissions are representative of normal operations;

c. if the emissions are not representative of normal operations, the cause of the abnormal emissions;

d. the total duration of any visible emissions incident; and

e. any corrective actions taken to minimize or eliminate the visible emissions.

If visible emissions are present, a visible emissions incident has occurred. The observer does not have to document the exact start and end times for the visible emissions incident under item (d) above or continue the daily check until the incident has ended. The observer may indicate that the visible emissions incident was continuous during the observation period (or, if known, continuous during the operation of the emissions unit). With respect to the documentation of corrective actions, the observer may indicate that no corrective actions were taken if the visible emissions were representative of normal operations, or specify the minor corrective actions that were taken to ensure that the emissions unit continued to operate under normal conditions, or specify the corrective actions that were taken to eliminate abnormal visible emissions.

(3) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

e) Reporting Requirements

(1) The permittee shall submit semiannual written reports that identify:

a. all days during which any visible particulate emissions were observed from the stack serving this emissions unit; and

b. any corrective actions taken to minimize or eliminate the visible particulate emissions.

These reports shall be submitted to the Director (the appropriate Ohio EPA District Office or local air agency) by January 31 and July 31 of each year and shall cover the previous 6-month period.

(2) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

(3) Unless other arrangements have been approved by the Director, all notifications and reports shall be submitted through the Ohio EPA's eBusiness Center: Air Services online web portal.

f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitations:

0.70 pound per hour and 3.07 TPY of PE/PM10.

Applicable Compliance Method:

The hourly emission limitation of 0.70 pound per hour was set based on Table I in OAC rule 3745-17-11 and a process weight rate of 142.6 pounds per hour for the process.

If required, the permittee shall demonstrate compliance with the lb/hr of 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. Emission Limitations:

67.9 pounds per batch and 13.21 TPY of OC until March 31, 2014.

Applicable Compliance Method:

Compliance with the pounds per batch OC emissions limitation shall be demonstrated by multiplying the uncontrolled OC pounds per batch* by one minus the 56.8% control efficiency of the condenser.

*The uncontrolled pounds per batch of OC are 157.1 pounds. This was provided in the permit application submitted June 7, 2013 by Amylin Ohio LLC based on

Detailed Emission Master Process Calculations testing done at that facility in October of 2012.

If required, the permittee shall demonstrate compliance with the pounds per batch OC 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 OC emissions limitation shall be determined by multiplying the maximum OC pounds per batch emissions by the maximum batches of operation (183) and converting to TPY by multiplying by 1 ton/2000 lb. An additional 7 tons of fugitive OC emissions are released from pumps, valves, flanges and other fittings based on Detailed Emission Master Process Calculations done at the Amylin facility in October of 2012.

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

(2) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

g) Miscellaneous Requirements

(1) None.