05/05/2026

No	TOXIC REVIEW
No	SYNTHETIC MINOR TO AVOID MAJOR NSR
No	CEMS
Yes	MACT/GACT
No	NSPS
No	NESHAPS
No	NETTING
No	MODELING SUBMITTED
Yes	SYNTHETIC MINOR TO AVOID TITLE V
Yes	FEDERALLY ENFORCABLE PTIO (FEPTIO)
No	SYNTHETIC MINOR TO AVOID MAJOR GHG

William Contenza
Olon USA, LLC
7528 Auburn Road
Concord, OH 44077

RE: DRAFT AIR POLLUTION PERMIT-TO-INSTALL AND OPERATE
Facility ID: 0243000241
Permit Number: P0140307
Permit Type: Initial Installation
County: Lake

Dear Permit Holder:

A draft of the Ohio Administrative Code (OAC) Chapter 3745-31 Air Pollution Permit-to-Install and Operate (PTIO) for the referenced facility has been issued for the emissions unit(s) listed in the Authorization section of the enclosed draft permit. This draft action is not an authorization to begin construction or modification of your emissions unit(s). The purpose of this draft is to solicit public comments on the permit. A public notice will appear in the Ohio Environmental Protection Agency Weekly Review and Public Notices website, ***Weekly Review and Public Notices***. A copy of the public notice and the draft permit are enclosed. This permit can be accessed electronically on the Ohio EPA document search webpage: ***eDocument Search | Ohio Environmental Protection Agency***. Comments will be accepted as a marked-up copy of the draft permit or in narrative format. Any comments must be sent to the following:

Andrea Moore
Permit Review/Development Section
Ohio EPA, DAPC
50 West Town Street Suite 700
PO Box 1049
Columbus, Ohio 43216-1049

and

Ohio EPA DAPC, Northeast District Office
2110 East Aurora Rd.
Twinsburg, OH 44087

Comments and/or a request for a public hearing will be accepted within 30 days of the date the notice appears on the Ohio EPA Weekly Review and Public Notices website, ***Weekly Review and Public Notices | Ohio Environmental Protection Agency***. You will be notified if a public hearing is scheduled. A decision on issuing a final permit-to-install will be made after consideration of comments received and oral testimony if a public hearing is conducted. Any permit fee that will be due upon issuance of a final Permit-to-Install is indicated in the Authorization section. Please do not submit any payment now. If you have any questions, please contact Ohio EPA DAPC, Northeast District Office at (330)963-1200.

Sincerely,

Robert Hodanbosi

Robert Hodanbosi
Chief, Division of Air Pollution Control

cc: U.S. EPA Region 5 Via E-Mail Notification
Ohio EPA-NEDO; Pennsylvania; Canada

PUBLIC NOTICE

The following matters are the subject of this public notice by the Ohio Environmental Protection Agency. The complete public notice, including any additional instructions for submitting comments, requesting information, a public hearing, or filing an appeal may be obtained at: ***Weekly Review and Public Notices | Ohio Environmental Protection Agency*** or Hearing Clerk, Ohio EPA, 50 W. Town St., Columbus, Ohio 43215. Ph: 614-644-3037 email: ***HClerk@epa.ohio.gov***

Draft Air Pollution Permit-to-Install and Operate Initial Installation

Olon USA, LLC
7528 AUBURN ROAD

Concord, OH 44077-1000

ID#: P0140307
Date of Action: 05/05/2026
Permit Desc: Federally Enforceable Permit-to-Install and Operate (FEPTIO) to install 2 new chemical reactors and a filter dryer for use in commercial manufacturing to its existing research and development facility in Concord, Ohio.

The permit and complete instructions for requesting information or submitting comments may be obtained at: https://epa.ohio.gov/help-center/edocument-search/edocument-search by entering the permit # or by contacting: Andrew Marantides, Ohio EPA DAPC, Northeast District Office, 2110 East Aurora Rd., Twinsburg, OH 44087. Ph: (330)963-1200

Permit Strategy Write-Up

1. Check all that apply:

   ☒ Synthetic Minor Determination

   ☐ Netting Determination

2. Source Description:

   Olon USA, LLC is a pharmaceutical research and development (R&D) facility and intends to construct sources for the purposes of commercial pharmaceutical manufacturing facility at the R&D facility. Olon USA, LLC has applied for a Federally Enforceable Permit-to-Install and Operate (FEPTIO) to install 2 new chemical reactors and a filter dryer and modify four existing chemical reactors and one filter dryer for commercial manufacturing at its existing research and development facility in Concord, Ohio. The existing R&D emissions units are also being issued a FEPTIO modification to take federally enforceable emission limits below major source thresholds

3. Facility Emissions and Attainment Status:

   Facility is taking a synthetic minor restriction on VOC, individual HAP and combined HAP emissions with a facility-wide limit that includes PBRs, permit exempt and de minimis units to stay under major source thresholds to avoid Title V and Maximum Achievable Control Technology (MACT) requirements.

   Facility is located in Lake County, which is in nonattainment for ozone and is a designated maintenance area for SO_2.

4. Source Emissions:

   Synthetic Minor limitations ensure facility-wide VOC emissions shall not exceed 49.0 TPY, individual HAP emissions shall not exceed 9.9 TPY and combined HAP emissions do not exceed 24.9 TPY.

5. Conclusion:

   Facility-wide VOC, individual HAP and combined HAP emissions are limited to 49.0 TPY VOC, individual HAP emissions shall not exceed 9.9 TPY and combined HAP emissions do not exceed 24.9 TPY based on a rolling 12-month period. Emissions of de minimis, PBR and permit exempt sources being included in the facility wide rolling 12-month summation limit.

6. Please provide additional notes or comments as necessary:

   None

7. Total Permit Allowable Emissions Summary (for informational purposes only):

Pollutant	Tons Per Year
VOC	49.0
Individual HAP	9.9
Combined HAP	24.9

Ohio Environmental Protection Agency

DRAFT

Division of Air Pollution Control
Permit-to-Install and Operate
for
Olon USA, LLC

Facility ID:	0243000241
Permit Number:	P0140307
Permit Type:	Initial Installation
Issued:	05/05/2026
Effective:	To be entered upon final issuance
Expiration:	To be entered upon final issuance

Ohio Environmental Protection Agency

Division of Air Pollution Control

Permit-to-Install and Operate

for

Olon USA, LLC

Table of Contents

Authorization

Facility ID:	0243000241
Application Number(s):	A0081822, A0081000, A0081766A0081822, A0081000, A0081766
Permit Number:	P0140307
Permit Description:	Federally Enforceable Permit-to-Install and Operate (FEPTIO) to install 2 new chemical reactors and a filter dryer for use in commercial manufacturing to its existing research and development facility in Concord, Ohio.
Permit Type:	Initial Installation
Permit Fee:	$900.00 *DO NOT send payment at this time, subject to change before final issuance*
Issue Date:	05/05/2026
Effective Date:	To be entered upon final issuance
Expiration Date:	To be entered upon final issuance
Permit Evaluation Report (PER) Annual Date:	To be entered upon final issuance

This document constitutes issuance of a Permit-to-Install and Operate for the emissions unit(s) identified on the following page to:

Olon USA, LLC
7528 AUBURN ROAD
Concord, OH 44077-1000

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

Ohio EPA DAPC, Northeast District Office
2110 East Aurora Rd.
Twinsburg, OH 44087
(330)963-1200

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

John Logue
Director

Authorization (continued)

Permit Number: P0140307

Permit Description: Federally Enforceable Permit-to-Install and Operate (FEPTIO) to install 2 new chemical reactors and a filter dryer for use in commercial manufacturing to its existing research and development facility in Concord, Ohio.

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

Emissions Unit ID:	**P050**
Company Equipment ID:	FD-23000
Superseded Permit Number:	
General Permit Category and Type:	Not Applicable

Group Name: 5000L Reactors

Emissions Unit ID:	**P048**
Company Equipment ID:	R-22000
Superseded Permit Number:	
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	**P049**
Company Equipment ID:	R-23000
Superseded Permit Number:	
General Permit Category and Type:	Not Applicable

List of Commonly Used Abbreviations

AP-42 = U.S. EPA's Compilation of Air Pollution Emissions Factors	HVLP = high volume, low pressure	PER = Permit Evaluation Report
ASTM = American Society for Testing and Materials	LAER = lowest achievable emission rate	PM = particulate matter
BACT = Best Available Control Technology	lb(s)/hr = pound(s) per hour	PM_{10} = particulate matter with an aerodynamic diameter less than or equal to 10 microns
BAT = Best Available Technology	LDAR = leak detection and repair	$PM_{2.5}$ = particulate matter with an aerodynamic diameter less than or equal to 2.5 microns
CAA = Clean Air Act	LPG = liquefied petroleum gas/propane	ppb = parts per billion
CAM = compliance assurance monitoring	MACT = maximum achievable control technology	ppm = parts per million
CEMS = continuous emissions monitoring system	MAGLC = maximum acceptable ground level concentration	PSD = Prevention of Significant Deterioration
CFC = chlorofluorocarbon	mg/m3 = milligrams per cubic meter	psi = pounds per square inch
CFR = Code of Federal Regulations	MM = million	psia = pounds per square inch absolute
CH_4 = methane	MMBtu = million British Thermal Units	PTE = potential-to-emit
CI = compression ignition	MSDS = material safety data sheet	PTI = Permit-to-Install
CO = carbon monoxide	MSW = municipal solid waste	PTIO = Permit-to-Install and Operate
CO_2 = carbon dioxide	NAAQS = National Ambient Air Quality Standard	PTO = Permit-to-Operate
COM = continuous opacity monitor	NESHAP = National Emission Standard for Hazardous Air Pollutants	PWR = process weight rate
DAPC = Division of Air Pollution Control	NG = natural gas	RACM = reasonably available control measures
DO/LAA = District Office/Local Air Agency	ng/m3 = nanograms per cubic meter	RACT = reasonably available control technology
dscf = dry standard cubic foot	NH_3 = ammonia	RATA = relative accuracy test audit
EAC = emissions activity category	NMHC = non-methane hydrocarbons	RTO = regenerative thermal oxidizer
eDocs = electronic documents database	NMOC = non-methane organic compound	SB265 = Senate Bill 265
ERAC = Environmental Review Appeals Commission	NO = nitrogen oxide	scfm = standard cubic feet per minute
ESP = electrostatic precipitator	NO_2 = nitrogen dioxide	SI = spark ignition
EU = emissions unit	NO_x = nitrogen oxides	SIP = State Implementation Plan
FEPTIO = Federally Enforceable Permit-to-Install and Operate	NSPS = New Source Performance Standard	SO_2 = sulfur dioxide
FER = Fee Emissions Report	NSR = New Source Review	SSMP = startup, shutdown, and malfunction plan
FR = Federal Register	NTV = Non-Title V	TDS = total dissolved solids
GACT = generally achievable control technology	O&M = operation and maintenance	TLV = threshold limit value
GHG = greenhouse gases	OAC = Ohio Administrative Code	TO = thermal oxidizer
gr/dscf = grains per dry standard cubic foot	OC = organic compound	TPH = ton(s) per hour
H_2S = hydrogen sulfide	Ohio EPA = Ohio Environmental Protection Agency	TPY = ton(s) per year
H_2SO_4 = sulfuric acid	ORC = Ohio Revised Code	TSP = total suspended particulates
HAP = hazardous air pollutant	Pb = lead	VE = visible emissions
HCl = hydrogen chloride	PBR = Permit-By-Rule	VMT = vehicle miles traveled
HF = hydrogen fluoride	PCB = polychlorinated biphenyl	VOC = volatile organic compound
Hg = mercury	PE = particulate emissions	WPP = work practice plan
hp = horsepower	PEMS = predictive emissions monitoring system	µg/m3 = micrograms per cubic meter

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:

a) 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.

b) 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 (either electronically through Ohio EPA's eBusiness Center: Air Services web service or 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 once by 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 permit evaluation report (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 of this permit 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 Ohio EPA DAPC, Northeast District Office 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/her 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 shut down 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, the new owner or operator must follow the procedures in OAC Chapter 3745-31-07, including notifying Ohio EPA or the local air agency of the change in ownership or operator within thirty days of the transfer date. Any transferee of this permit shall 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 PTI issued in accordance with ORC 3704.03(F) and a PTO issued in accordance with ORC 3704.03(G).

   a) For the purpose of a PTI document, the facility-wide T&C 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 PTO document, the facility-wide T&C identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

      (1) Facility-wide VOC and HAP Restrictions

      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(D) [Synthetic minor to avoid Major Source MACT and Title V]	See B.1.b)(2).

      (2) Additional Terms and Conditions

      a. The facility-wide emissions (including, but not limited to, de minimis, exempt, and combustion sources) shall not exceed the following:

         i. 49.0 TPY, based upon a rolling, 12-month summation of VOC emissions;

         ii. 9.9 TPY, based upon a rolling, 12-month summation of each individual HAP (HAPi) emissions; and

         iii. 24.9 TPY, based upon a rolling ,12-month summation of total combined HAPs emissions.

      b. The emissions of VOC from all permitted EUs and all other emission sources at the facility, including but not limited to de minimis, exempt, and combustion sources, shall not exceed 49.0 TPY, based upon a rolling, 12-month summation of the VOC emissions. To ensure enforceability during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall not exceed the emission levels specified in the following table:

Month(s)	Maximum Allowable Facility-Wide Emissions (Tons)
1	16.4

1-2	20.5
1-3	24.6
1-4	28.7
1-5	32.8
1-6	36.9
1-7	41.0
1-8	45.1
1-9	49.0
1-10	49.0
1-11	49.0
1-12	49.0

After the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, compliance with the annual emission limitation for all permitted EUs and all other emission sources at the facility, including but not limited to de minimis, exempt, and combustion sources, shall be based upon a rolling, 12-month summation of the VOC emissions.

c. The emissions of HAP_i from all permitted EUs and all other emission sources at the facility, including but not limited to de minimis, exempt, and combustion sources, shall not exceed 9.9 TPY, based upon a rolling, 12-month summation of each single HAP emissions. To ensure enforceability during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall not exceed the emission levels specified in the following table:

Month(s)	Maximum Allowable Facility-Wide Emissions (Tons)
1	2.5
1-2	3.5
1-3	4.5
1-4	5.5
1-5	6.5
1-6	7.5
1-7	8.5
1-8	9.5
1-9	9.9
1-10	9.9
1-11	9.9
1-12	9.9

After the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, compliance with the annual emission limitation for all permitted EUs all other emission sources at the facility, including but not limited to de minimis, exempt, and combustion sources, shall be based upon a rolling, 12-month summation of each individual HAP emissions.

d. The emissions of combined HAPs from all permitted EUs and all other emission sources at the facility, including but not limited to de minimis, exempt, and combustion sources, shall not exceed 24.9 TPY, based upon a rolling, 12-month summation of the combined HAPs emissions. To ensure enforceability during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall not exceed the emission levels specified in the following table:

Month(s)	Maximum Allowable Facility-Wide Emissions (Tons)
1	6.2
1-2	8.5
1-3	10.8
1-4	13.1
1-5	15.4
1-6	17.7
1-7	20
1-8	22.3
1-9	24.9
1-10	24.9
1-11	24.9
1-12	24.9

After the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, compliance with the annual emission limitation for all permitted EUs and all other emission sources at the facility, including but not limited to de minimis, exempt, and combustion sources, shall be based upon a rolling, 12-month summation of the combined HAPs emissions.

c) Operational Restrictions

(1) None.

d) Monitoring and/or Recordkeeping Requirement:

(1) The permittee shall collect and record the following facility-wide information each month:

a. the monthly facility-wide VOC emissions, in tons;

b. the rolling, 12-month period facility-wide VOC emissions, in tons;

c. the monthly facility-wide each individual HAP emissions, in tons;

d. the rolling, 12-month period facility-wide each individual HAP emissions, in tons;

e. the monthly facility-wide total combined HAPs emissions, in tons; and

f. the rolling, 12-month period facility-wide total combined HAPs, in tons.

*Note: From each de minimis and permit exempt sources, actual VOC, individual HAP and combined HAP emissions (tons) can be maintained or the VOC, individual HAP and combined HAP potential to emit (TPY) from each de minimis or permit exempt EU for which monthly records of actual VOC emissions are not maintained.

e) Reporting Requirements

(1) The permittee shall submit quarterly deviation (excursion) reports that identify:

a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:

i. The facility-wide emissions shall not exceed the following:

(a) 49.0 TPY, based upon a rolling, 12-month summation of VOC emissions;

(b) 9.9 TPY, based upon a rolling, 12-month summation of each individual HAP emissions; and

(c) 24.9 TPY, based upon a rolling ,12-month summation of total combined HAPs emissions.

b. the probable cause of each deviation (excursion);

c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and

d. the magnitude and duration of each deviation (excursion).

If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) occurred during the quarter.

The quarterly reports shall be submitted each year by January 31 (covering October to December), April 30 (covering January to March), July 31 (covering April to June), and October 31 (covering July to September), unless an alternative schedule has been established and approved by the Director (the appropriate District Office or local air agency).

f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in B.1.b)(2) of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitation:

The facility-wide VOC emissions shall not exceed 49.0 TPY, based upon a rolling, 12-month summation of VOC emissions;

Applicable Compliance Method:

Compliance shall be based upon the record keeping specified in Section d)(1) of these terms and conditions.

b. Emission Limitation:

The facility-wide HAP_i emissions shall not exceed 9.9 TPY, based upon a rolling, 12-month summation of each individual HAP emissions.

Applicable Compliance Method:

Compliance shall be based upon the record keeping specified in Section d)(1) of these terms and conditions.

c. Emission Limitation:

The facility-wide combined HAPs emissions shall not exceed 24.9 TPY, based upon a rolling, 12-month summation of total combined HAPs emissions.

Applicable Compliance Method:

Compliance shall be based upon the record keeping specified in Section d)(1) of these terms and conditions.

2. The permittee is exempted from the following federal requirements, as described below:

a) NSPS-40 CFR Part 60, Subpart RRR, Standards of Performance for Volatile OC Emissions from SOCMI Reactor Processes: Exempt based on design/operation as batch. (See Section 60.700 (c)(1)).

b) NSPS – 40 CFR Part 60, Subpart VV, Standards of Performance for Equipment Leaks of VOC in the SOCMI for which Construction, Reconstruction, or Modification Commenced After January 5, 1981, and on or Before November 7, 2006 (See Section 60.480(d)(2)). The owner or operator shall maintain records as required in §60.486(i): An analysis demonstrating the design capacity of the affected facility.

c) NSPS – 40 CFR Part 60, Subpart VVa, Standards of Performance for Equipment Leaks of VOC in the SOCMI for which Construction, Reconstruction, or Modification Commenced After November 7, 2006 (See Section 60.480a(d)(2)). The owner or operator shall maintain records as required in §60.486a(i): An analysis demonstrating the design capacity of the affected facility.

d) NSPS – 40 CFR Part 60, Subpart VVb Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry for Which Construction, Reconstruction, or Modification Commenced After April 25, 2023: The facility does not produce these listed chemicals as either intermediates or final products and is therefore not subject to the requirements of this subpart.

e) MACT- 40 CFR Part 63, Subpart GGG, National Emission Standards for Pharmaceuticals Production: Rule does not apply since the facility is not a major source of HAPs (see Section 63.1250(a)(1)(ii)).

3. The Ohio EPA has determined that this facility operates affected sources that could be subject to the requirements of 40 CFR Part 63, Subpart VVVVVV, the NESHAP for Chemical Manufacturing Area Sources.

Ohio EPA is not accepting the delegation authority to implement and enforce the area source NESHAP standard. The area source NESHAP standard is implemented and enforced by U.S. EPA, Region 5. The promulgated version of this NESHAP standard and the 40 CFR Part 63, General Provisions may be accessed via the Internet from the Electronic Code of Federal Regulations (e-CFR) website http://www.ecfr.gov/ or by contacting the appropriate Ohio EPA, DO/LAA.

The following affected sources will be subject to the area source requirements of this NESHAP standard: EUs P048, P049 and P050 if compounds listed in Table 1 of the standard are used. If the facility decides to use compounds listed in Table 1, it will bear the responsibility for notification requirements to Region 5 under the standard.

4. All applications, notifications, or reports required in writing are to be submitted through Ohio EPA's eBusiness Center: Air Services online web portal. Hardcopy submissions will be accepted on an as-needed basis if the permittee cannot submit the required documents through Air Services. In the event of a hardcopy submission, the post-marked date or the date the document is delivered in person will be recognized as the date submitted. Electronic submittal of applications, notifications, or reports to Ohio EPA fulfills the requirement to submit information to the director, the appropriate Ohio EPA DO/LAA, and/or any other individual or organization identified as a recipient unless otherwise specified in this permit. Consistent with OAC rule 3745-15-03, the application, notification or report is considered submitted on the date the submittal is successful using a valid electronic signature. Signature by the signatory authority may be represented as provided through procedures established in Air Services.

C. Emissions Unit Terms and Conditions

1. P050, FD-23000

Operations, Property and/or Equipment Description:

330 Liter Filter Dryer

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) b)(1)g. and d)(8).

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)(a)(ii)	The BAT requirements under OAC rule 3745-31-05(A)(3) do not apply to the VOC emissions from this air contaminant source since the PTE is less than 10 TPY when taking into account the requirements established pursuant to OAC rule 3745-21-09(W) and the calculation method in b)(2)b. below.
b.	OAC rule 3745-31-05(D)	See b)(2)b. and B.1.b)(1).
c.	OAC rules 3745-31-05(F)	See c)(6) and c)(7).
d.	OAC rule 3745-21-09(W)	See b)(2)a., c)(1) and c)(2).
e.	OAC rule 3745-21-23	See b)(2)c., c)(3), c)(4) and c)(5).
f.	OAC rule 3745-21-14	See b)(2)b. and b)(2)d.
g.	OAC rule 3745-114-01 ORC 3704.03(F)	See d)(8).

(2) Additional Terms and Conditions

a. The discharge of VOC emissions into the ambient air from any reactor, distillation operation, crystallizer, centrifuge or vacuum dryer is to be controlled by a surface condenser which has an outlet gas concentration of VOC not exceeding fifty thousand parts per million by volume (ppmv).

i. The dryer shall be operated under vacuum during operation, resulting in a sealed condition, so the EU does not have VOC emissions collected by a production equipment exhaust system. Since the operations are conducted in a closed system and no VOC emissions are collected by a production equipment exhaust system, the requirements of 3745-21-09(W)(1)(b) do not apply.

b. Olon USA, LLC is a batch chemical manufacturing facility. The PTE is based upon the August 29, 1996 guidance memorandum by John Seitz entitled "Clarification of Methodology for Calculating PTE for Batch Chemical Production Operations". Though

the short-term emissions calculate to higher emissions when estimated using 8,760 hours per year, the other equipment used for projects at this facility physically inhibits this EU's operation such that the PTE is physically limited. Facility-wide PTE is also physically limited due to the reason described above and other process "bottlenecks".

i. Batch chemical reactions are conducted in reactors P048 and P049. EU P050 (FD-23000) is used to isolate solid chemical product from a slurry. The slurry is prepared in P048 and/or P049 and then transferred to P050. Liquid filtrate is collected in drums for disposal. Solids may be rinsed or re-slurried with additional solvent utilizing the filter dryer's agitator to provide mixing. Once solids are isolated, remaining solvent is removed using heat and vacuum/solvent recovery system which is vented to a wet scrubber. Dry solid product is discharged into a continuous liner inside an integrated glove box.

c. In accordance with OAC rule 3745-21-23(C)(1), the permittee shall not use a solvent to perform solvent cleaning operations unless the solvent complies with the following applicable VOC-content limitation for medical devices and pharmaceuticals:

i. Product cleaning during manufacturing process:

(a) Medical devices and pharmaceuticals: 6.7 lbs/gal, as employed.

ii. Repair and maintenance cleaning medical devices and pharmaceuticals:

(a) Tools, equipment and machinery: 6.7 lbs/gal, as employed.

(b) General work surfaces: 5.0 lbs/gal, as employed.

d. The requirements of OAC rule 3745-21-14 do not apply to this facility since the facility- wide emissions are less than 50 TPY when calculating the emissions based on the batch process utilization method in b)(2)b. above and taking into account the requirements established pursuant to the OAC rule 3745-31-05(D) restrictions.

c) Operational Restrictions

(1) Any in-process tank which contains a VOC is to be equipped with a cover which remains closed, except when production, sampling, maintenance or inspection procedures require access to said tank.

(2) Any leak in which a VOC is observed to be running or dripping from a vessel or other equipment is to be repaired as soon as possible, but no later than the first time said equipment is off-line for a period of time long enough to complete the repair.

(3) The owner or operator of a facility that is subject to OAC rule 3745-21-23 shall employ only the following cleaning devices and methods:

a. Wipe cleaning.

b. Closed containers or hand-held spray bottles from which solvents are applied without a propellant-induced force.

c. Cleaning equipment which has a solvent container that can be, and is closed during cleaning operations, except when depositing and removing objects to be cleaned, and is closed during non-operation with the exception of maintenance and repair to the cleaning equipment itself.

d. Remote reservoir cleaner, if the operator of the cleaner complies with all of the following:

i. Prevents solvent vapors from escaping from the solvent container by using such devices as a cover or a valve when the remote reservoir is not being used, cleaned, or repaired.

ii. Directs solvent flow in a manner that will prevent liquid solvent from splashing outside of the remote reservoir cleaner.

iii. Does not clean porous or absorbent materials, such as cloth, leather, wood, or rope.

iv. Uses only solvent containers free of all liquid leaks. Auxiliary equipment, such as pumps, pipelines, or flanges, shall not have any liquid leaks, visible tears, or cracks. Any liquid leak, visible tear, or crack detected shall be repaired within one calendar day, or the leaking section of the remote reservoir cold cleaner shall be drained of all solvent and shut down until it is replaced or repaired.

e. Non-atomized solvent flow method where the cleaning solvent is collected in a container or a collection system which is closed except for solvent collection openings and, if necessary, openings to avoid excessive pressure build-up inside the container.

f. Solvent flushing method where the cleaning solvent is discharged into a container which is closed except for solvent collection openings and, if necessary, openings to avoid excessive pressure build-up inside the container. The discharged solvent from the equipment must be collected into containers without atomizing into the open air. The solvent may be flushed through the system by air or hydraulic pressure, or by pumping.

(4) The owner or operator of a facility that is subject to OAC rule 3745-21-23 is prohibited from atomizing any solvent unless the emissions are vented to VOC emission control equipment that meets paragraph (C)(5) of OAC rule 3745-21-23.

(5) All VOC-containing solvents used in solvent cleaning operations shall be stored in non-absorbent, non-leaking containers which shall be kept closed at all times except when filling or emptying. It is recommended that cloth and paper moistened with VOC-containing solvents be stored in closed, non-absorbent, non-leaking containers.

(6) The EU shall exhaust to a wet scrubber to minimize or reduce nuisance odors.

(7) When using chlorine, hydrogen chloride, hydrogen bromide, t-butylamine and/or like compounds, in this EU, a scrubber shall be employed. The pH of the scrubber liquor shall be maintained at a pH of 10 or greater when using chlorine, hydrogen chloride, hydrogen bromide and/or like compounds. The pH of the scrubber liquor shall be maintained at a pH of 4 or less when using t-butylamine or like compounds.

d) Monitoring and/or Recordkeeping Requirements

(1) The owner or operator of a solvent cleaning operation that is subject to one or more of the VOC-content limitations specified in paragraph (C)(1) of OAC rule 3745-21-23 shall collect and record the following information each month for each cleaning material subject to a VOC-content limitation and shall maintain the information at the facility for a period of five years:

a. The name and identification of each cleaning material and the associated solvent cleaning activity.

b. The VOC content, based upon USEPA Method 24, of each cleaning material, in pounds per gallon of material, as employed or the VOC composite partial vapor pressures of the solvents or solvent solutions used in the industrial cleaning operations.

(2) In order to maintain compliance with the applicable emissions limitation(s) contained in this permit, the acceptable average temperature of the exhaust gases from the condenser, for any three-hour block of time, shall not be more than 11ºF above the average temperature measured during the most recent performance test that demonstrated the EU(s), controlled by the condenser, was/were in compliance. Until compliance testing has been conducted, the condenser shall be operated and maintained per the manufacturer's recommendations.

(3) The permittee shall properly install, operate, and maintain a continuous temperature monitor and recorder which measures and records the temperature of the exhaust gases from the condenser when the EU(s) is/are in operation, including periods of startup and shutdown. Units shall be in degrees Fahrenheit. The accuracy for each thermocouple, monitor and recorder shall be guaranteed by the manufacturer to be within ± 1% of the temperature being measured or ± 5ºF, whichever is greater. The temperature monitor and recorder shall be installed, calibrated, operated, and maintained per the manufacturer's recommendations, instructions, and operating manuals, with any modifications deemed necessary by the permittee. The permittee shall collect and record the following information each day the EU(s) is/are in operation:

a. All three-hour blocks of time, when the EU(s) controlled by the condenser was/were in operation, during which the average temperature of the exhaust gases from the condenser was more than 11ºF above the average temperature measured during the most recent performance test that demonstrated the EU(s) was/were in compliance or the manufacturer's specifications until such time testing is performed; and

b. A log or record of operating time for the capture (collection) system, condenser, monitoring equipment and the associated EU(s).

These records shall be maintained at the facility for a period of three years.

(4) Whenever the monitored temperature of the exhaust gases from the condenser deviates from the range/limit established per this permit, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. The date and time the deviation began;

b. The magnitude of the deviation at that time;

c. The date the investigation was conducted;

d. The name(s) of the personnel who conducted the investigation; and

e. The findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range/limit specified in this permit, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

f. A description of the corrective action;

g. The date corrective action was completed;

h. The date and time the deviation ended;

i. The total period of time (in minutes) during which there was deviation;

j. The temperature readings of the exhaust gas from condenser immediately after the corrective action was implemented; and

k. The name(s) of the personnel who performed the work.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The exhaust gas temperature range/limit is effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA DO/LAA. The permittee may request revisions to the permitted exhaust gas temperature range/limit based upon information obtained during future performance tests that demonstrate compliance with the allowable VOC emissions rate for the controlled EU(s). In addition, approved revisions to the exhaust gas temperature range/limit will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of an administrative modification.

(5) The permittee shall keep the following daily records for all materials used in this EU:

a. the identification of the chemical compound and its physical state; and

b. the permittee shall maintain records for EU P050, that document any time periods when the wet scrubber was not in service when used to minimize or reduce nuisance odors. These records shall be maintained for a period of not less than 5 years and shall be made available to the Ohio EPA upon request.

(6) The permittee shall assure that the pH of the scrubber liquor is adequate when the EU is being operated using chlorine, hydrogen chloride, hydrogen bromide, t-butylamine and/or like compounds, to assure that these compounds are effectively removed from the vent. This would typically be a pH greater than or equal to 10 for chlorine, hydrogen chloride, hydrogen bromide and like compounds; and a pH less than or equal to 4 for t-butylamine and like compounds.

The following may be used to assure control of the above compound emissions:

a. measuring the pH of the scrubber liquor before and after each reaction; or

b. continuously monitoring and recording the pH of the scrubber liquor using equipment that is properly operated and maintained; or

c. when the stoichiometry and operational specifics are known, document the quantity of acid or base charged along with the stoichiometry.

(7) Whenever the monitored value of the pH deviates from the range specified, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. the date and time the deviation began;

b. the magnitude of the deviation at that time;

c. the date(s) the investigation was conducted; and

d. the findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range specified below, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

e. a description of the corrective action;

f. the date it was completed;

g. the date and time the deviation ended;

h. the total period of time (in minutes) during which there was a deviation; and

i. the pH readings immediately after the corrective action.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The permittee shall record and maintain a log or record of operating time for the EU and the scrubber.

(8) Modeling to demonstrate compliance with the Toxic Air Contaminant Statute, ORC 3704.03(F)(4)(b), was not necessary because the EU's maximum annual emissions for each toxic air contaminant, as defined in OAC rule 3745-114-01, will be less than 1 TPY. OAC Chapter 3745-31 requires a permittee to apply for and obtain a new or modified FEPTIO prior to making a modification as defined by OAC rule 3745-31-01. The permittee is hereby advised that changes in the composition of the materials or use of new materials, that would cause the emissions of any toxic air contaminant to increase to above 1 TPY, may require the permittee to apply for and obtain a new FEPTIO.

e) Reporting Requirements

(1) The reports contained in this permit shall be submitted in accordance with the reporting requirements specified in Section A, Standard Terms and Conditions.

(2) In accordance with OAC rule 3745-21-09(B)(4)(c), the permittee shall submit quarterly summaries that identify:

a. All three-hour blocks of time when the EU(s) was/were in operation during which the average temperature of the exhaust gases from the condenser was more than 11ºF above the average temperature of the exhaust gases measured during the most recent performance test that demonstrated the EU(s) was/were in compliance;

b. Any records of downtime (date and length of time) for the capture (collection) system, the condenser and/or the monitoring equipment when the EU(s) was/were in operation; and

c. A log of the operating time for the capture system, condenser, monitoring equipment, and EU(s).

These quarterly reports shall be submitted by April 30, July 31, October 31, and January 31, and shall cover the records for the previous calendar quarters.

(3) Any owner or operator of a solvent cleaning operation that is subject to one or more of the VOC-content limitations specified in paragraph (C)(1) of OAC rule 3745-21-23 shall notify the appropriate Ohio EPA DO/LAA of any record maintained in accordance with paragraph (G)(1) of OAC rule 3745-21-23 showing the use of noncomplying solvents. A copy of such record shall be sent to the appropriate Ohio EPA DO/LAA within thirty days following the end of the month in which the use of noncomplying solvents occurs.

(4) The permittee shall submit an annual PER to Ohio EPA by the due date identified in the Authorization section of this permit. The PER shall cover a reporting period of no more than 12 months for each air contaminant source identified in this permit.

(5) The permittee shall identify in the annual PER the following information concerning the operations of the scrubber during the 12-month reporting period for this EU:

a. each period of time when the pH of the scrubber liquor was outside the acceptable range;

b. an identification of any time periods when one of the wet scrubbers was not in service for EU P050, when used to minimize or reduce nuisance odors;

c. an identification of each incident of deviation described in e)(5)a. where a prompt investigation was not conducted;

d. an identification of each incident of deviation described in e)(5)a. where prompt corrective action, that would bring the pH into compliance with the acceptable range, was determined to be necessary and was not taken;

e. an identification of each incident of deviation described in e)(5)a. where proper records were not maintained for the investigation and/or the corrective action.

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 Limitation:

The discharge of VOC emissions into the ambient air from any reactor, distillation operation, crystallizer, centrifuge or vacuum dryer is to be controlled by a surface condenser which has an outlet gas concentration of VOC not exceeding fifty thousand parts per million by volume.

Applicable Compliance Method:

Compliance shall be demonstrated by emissions testing performed in accordance with the methods and procedures specified in f)(2).

b. Emission Limitation:

In accordance with OAC rule 3745-21-23(C)(1), the permittee shall not use a solvent to perform solvent cleaning operations unless the solvent complies with the following applicable VOC-content limitation for medical devices and pharmaceuticals:

i. Product cleaning during manufacturing process

(a) Medical devices and pharmaceuticals: 6.7 lbs/gal as employed.

ii. Repair and maintenance cleaning medical devices and pharmaceuticals:

(a) Tools, equipment and machinery: 6.7 lbs/gal as employed.

(b) General work surfaces: 5.0 lbs/gal as employed.

Applicable Compliance Method:

Compliance shall be demonstrated by the record keeping requirements specified in d)(1).

(2) The permittee shall conduct, or have conducted, emissions testing for this EU per the following requirements:

a. The emission testing shall be conducted within 180 days after initial startup of the EU.

b. The emission testing shall be conducted to demonstrate compliance with the allowable concentration of VOC in the exhaust stream.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emissions rate(s):

Method 25 of 40 CFR Part 60, Appendix A; or

Method 25A of 40 CFR Part 60, Appendix A; and

Alternative U.S. EPA-approved test methods may be used with prior approval from the Ohio EPA.

d. During the emissions testing, the EU shall be operated under operational conditions approved in advance by the appropriate Ohio EPA DO/LAA. Operational conditions that may need to be approved include, but are not limited to, the production rate, the type of material processed, material make-up (solvent content, etc.) or control equipment operational limitations (burner temperature, precipitator voltage, etc.). In general, testing shall be done under *worst case* conditions expected during the life of the permit. As part of the information provided in the Intent to Test (ITT) notification form described below, the permittee shall provide a description of the EU operational conditions they will meet during the emissions testing and describe why they believe *worst case* operating conditions will be met. Prior to conducting the test(s), the permittee shall confirm with the appropriate Ohio EPA DO/LAA that the proposed operating conditions constitute *worst case*. Failure to test under the approved conditions may result in Ohio EPA not accepting the test results as a demonstration of compliance.

e. Not later than 30 days prior to the proposed test date(s), the permittee shall submit an ITT notification to the appropriate Ohio EPA DO/LAA. The ITT notification shall describe in detail the proposed test methods and procedures, the EU operating parameters, the time(s) and date(s) of the test(s) and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Ohio EPA DO/LAA's refusal to accept the results of the emission test(s).

f. Personnel from the appropriate Ohio EPA DO/LAA shall be permitted to witness the test(s), examine the testing equipment and acquire data and information necessary to ensure that the operation of the EU and the testing procedures provide a valid characterization of the emissions from the EU and/or the performance of the control equipment.

g. A comprehensive written report on the results of the emissions test(s) shall be signed by the person(s) responsible for the tests and submitted to the appropriate Ohio EPA DO/LAA within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA DO/LAA.

(3) Formulation data shall be used to determine the VOC contents of the materials employed for each final product and each cleanup material.

g) Miscellaneous Requirements

(1) None.

2. Emissions Unit Group - 6000L Reactors: P048 and P049

EU ID	Operations, Property and/or Equipment Description
P048	Pfaudler Reactor 6000 L
P049	Pfaudler Reactor 6000 L

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) b)(1)g. and d)(8).

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)(a)(ii)	The BAT requirements under OAC rule 3745-31-05(A)(3) do not apply to the VOC from this air contaminant source since the PTE is less than 10 TPY when taking into account the requirements established pursuant to OAC rule 3745-21-09(W) and the calculation method in b)(2)b. below.
b.	OAC rule 3745-31-05(D)	See b)(2)b. and B.1.b)(1).
c.	OAC rules 3745-31-05(F)	See c)(6) and c)(7).
d.	OAC rule 3745-21-09(W)	See b)(2)a., c)(1) and c)(2).
e.	OAC rule 3745-21-23	See b)(2)c., c)(3), c)(4) and c)(5).
f.	OAC rule 3745-21-14	See b)(2)b. and b)(2)d.
g.	OAC rule 3745-114-01 ORC 3704.03(F)	See d)(8).

(2) Additional Terms and Conditions

a. The discharge of VOC emissions into the ambient air from any reactor, distillation operation, crystallizer, centrifuge or vacuum dryer is to be controlled by a surface condenser which has an outlet gas concentration of VOC not exceeding fifty thousand parts per million by volume (ppmv).

i. The dryer shall be operated under vacuum, resulting in a sealed condition during operation, so the EU does not have VOC emissions collected by a production equipment exhaust system. Since the operations are conducted in a closed system and no VOC emissions are collected by a production equipment exhaust system, the requirements of 3745-21-09(W)(1)(b) do not apply.

b. Olon USA, LLC is a batch chemical manufacturing facility. The PTE is based upon the August 29, 1996 guidance memorandum by John Seitz entitled "Clarification of Methodology for Calculating PTE for Batch Chemical Production Operations". Though the short-term emissions calculate to higher emissions when estimated using 8,760 hours per year, the other equipment used for projects at this facility physically inhibits this EU's operation such that the PTE is physically limited. Facility-wide PTE is also physically limited due to the reason described above and other process "bottlenecks".

i. Batch chemical reactions are conducted in reactors P048 and P049. EU P050 (FD-23000) is used to isolate solid chemical product from a slurry. The slurry is prepared in P048 and/or P049 and then transferred to P050. Liquid filtrate is collected in drums for disposal. Solids may be rinsed or re-slurried with additional solvent utilizing the filter dryer's agitator to provide mixing. Once solids are isolated, remaining solvent is removed using heat and vacuum/solvent recovery system which is vented to a wet scrubber. Dry solid product is discharged into a continuous liner inside an integrated glove box.

c. In accordance with OAC rule 3745-21-23(C)(1), the permittee shall not use a solvent to perform solvent cleaning operations unless the solvent complies with the following applicable VOC-content limitation for medical devices and pharmaceuticals:

i. Product cleaning during manufacturing process:

(a) Medical devices and pharmaceuticals: 6.7 lbs/gal as employed.

ii. Repair and maintenance cleaning medical devices and pharmaceuticals:

(a) Tools, equipment and machinery: 6.7 lbs/gal as employed.

(b) General work surfaces: 5.0 lbs/gal as employed.

d. The requirements of OAC rule 3745-21-14 do not apply to this facility since the facility- wide emissions are less than 50 TPY when calculating the emissions based on the batch process utilization method in b)(2)b. above and taking into account the requirements established pursuant to the OAC rule 3745-31-05(D) restrictions.

c) Operational Restrictions

(1) Any in-process tank which contains a VOC is to be equipped with a cover which remains closed, except when production, sampling, maintenance or inspection procedures require access to said tank.

(2) Any leak in which a VOC is observed to be running or dripping from a vessel or other equipment is to be repaired as soon as possible, but no later than the first time said equipment is off-line for a period of time long enough to complete the repair.

(3) The owner or operator of a facility that is subject to OAC rule 3745-21-23 shall employ only the following cleaning devices and methods:

a. Wipe cleaning.

b. Closed containers or hand-held spray bottles from which solvents are applied without a propellant-induced force.

c. Cleaning equipment which has a solvent container that can be, and is closed during cleaning operations, except when depositing and removing objects to be cleaned, and is closed during non-operation with the exception of maintenance and repair to the cleaning equipment itself.

d. Remote reservoir cleaner, if the operator of the cleaner complies with all of the following:

e. Prevents solvent vapors from escaping from the solvent container by using such devices as a cover or a valve when the remote reservoir is not being used, cleaned, or repaired.

f. Directs solvent flow in a manner that will prevent liquid solvent from splashing outside of the remote reservoir cleaner.

g. Does not clean porous or absorbent materials, such as cloth, leather, wood, or rope.

h. Uses only solvent containers free of all liquid leaks. Auxiliary equipment, such as pumps, pipelines, or flanges, shall not have any liquid leaks, visible tears, or cracks. Any liquid leak, visible tear, or crack detected shall be repaired within one calendar day, or the leaking section of the remote reservoir cold cleaner shall be drained of all solvent and shut down until it is replaced or repaired.

i. Non-atomized solvent flow method where the cleaning solvent is collected in a container or a collection system which is closed except for solvent collection openings and, if necessary, openings to avoid excessive pressure build-up inside the container.

j. Solvent flushing method where the cleaning solvent is discharged into a container which is closed except for solvent collection openings and, if necessary, openings to avoid excessive pressure build-up inside the container. The discharged solvent from the equipment must be collected into containers without atomizing into the open air. The solvent may be flushed through the system by air or hydraulic pressure, or by pumping.

(4) The owner or operator of a facility that is subject to OAC rule 3745-21-23 is prohibited from atomizing any solvent unless the emissions are vented to VOC emission control equipment that meets paragraph (C)(5) of OAC rule 3745-21-23.

(5) All VOC-containing solvents used in solvent cleaning operations shall be stored in non-absorbent, non-leaking containers which shall be kept closed at all times except when filling or emptying. It is recommended that cloth and paper moistened with VOC-containing solvents be stored in closed, non-absorbent, non-leaking containers.

(6) The EUs shall exhaust to a wet scrubber to minimize or reduce nuisance odors.

(7) When using chlorine, hydrogen chloride, hydrogen bromide, t-butylamine and/or like compounds, in each EU, a scrubber shall be employed. The pH of the scrubber liquor shall be maintained at a pH of 10 or greater when using chlorine, hydrogen chloride, hydrogen bromide and/or like compounds. The pH of the scrubber liquor shall be maintained at a pH of 4 or less when using t-butylamine or like compounds.

d) Monitoring and/or Recordkeeping Requirements

(1) The owner or operator of a solvent cleaning operation that is subject to one or more of the VOC-content limitations specified in paragraph (C)(1) of OAC rule 3745-21-23 shall collect and record the following information each month for each cleaning material subject to a VOC-content limitation and shall maintain the information at the facility for a period of five years:

a. The name and identification of each cleaning material and the associated solvent cleaning activity.

b. The VOC content, based upon USEPA Method 24, of each cleaning material, in pounds per gallon of material, as employed or the VOC composite partial vapor pressures of the solvents or solvent solutions used in the industrial cleaning operations.

(2) In order to maintain compliance with the applicable emissions limitation(s) contained in this permit, the acceptable average temperature of the exhaust gases from the condenser, for any three-hour block of time, shall not be more than 11ºF above the average temperature measured during the most recent performance test that demonstrated the EU(s), controlled by the condenser, was/were in compliance. Until compliance testing has been conducted, the condenser shall be operated and maintained per the manufacturer's recommendations.

(3) The permittee shall properly install, operate, and maintain a continuous temperature monitor and recorder which measures and records the temperature of the exhaust gases from the condenser when the EU(s) is/are in operation, including periods of startup and shutdown. Units shall be in degrees Fahrenheit. The accuracy for each thermocouple, monitor and recorder shall be guaranteed by the manufacturer to be within + 1% of the temperature being measured or + 5ºF, whichever is greater. The temperature monitor and recorder shall be installed, calibrated, operated, and maintained per the manufacturer's recommendations, instructions, and operating manuals, with any modifications deemed necessary by the permittee. The permittee shall collect and record the following information each day the EU(s) is/are in operation:

a. All three-hour blocks of time, when the EU(s) controlled by the condenser was/were in operation, during which the average temperature of the exhaust gases from the condenser was more than 11ºF above the average temperature measured during the most recent performance test that demonstrated the EU(s) was/were in compliance or the manufacturer's specifications until such time testing is performed; and

b. A log or record of operating time for the capture (collection) system, condenser, monitoring equipment and the associated EU(s).

These records shall be maintained at the facility for a period of three years.

(4) Whenever the monitored temperature of the exhaust gases from the condenser deviates from the range/limit established per this permit, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. The date and time the deviation began;

b. The magnitude of the deviation at that time;

c. The date the investigation was conducted;

d. The name(s) of the personnel who conducted the investigation; and

e. The findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range/limit specified in this permit, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

f. A description of the corrective action;

g. The date corrective action was completed;

h. The date and time the deviation ended;

i. The total period of time (in minutes) during which there was deviation;

j. The temperature readings of the exhaust gas from condenser immediately after the corrective action was implemented; and

k. The name(s) of the personnel who performed the work.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The exhaust gas temperature range/limit is effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA DO/LAA. The permittee may request revisions to the permitted exhaust gas temperature range/limit based upon information obtained during future performance tests that demonstrate compliance with the allowable VOC emissions rate for the controlled EU(s). In addition, approved revisions to the exhaust gas temperature range/limit will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of an administrative modification.

(5) The permittee shall keep the following daily records for all materials used, in each EU:

a. the identification of the chemical compound and its physical state; and

b. the permittee shall maintain records for EUs P048 and P049, that document any time periods when the wet scrubber was not in service when used to minimize or reduce nuisance odors. These records shall be maintained for a period of not less than 5 years and shall be made available to the Ohio EPA upon request.

(6) The permittee shall assure that the pH of the scrubber liquor is adequate when each EU is being operated using chlorine, hydrogen chloride, hydrogen bromide, t-butylamine and/or like compounds, to assure that these compounds are effectively removed from the vent. This would typically be a pH greater than or equal to 10 for chlorine, hydrogen chloride, hydrogen bromide and like compounds; and a pH less than or equal to 4 for t-butylamine and like compounds.

The following may be used to assure control of the above compound emissions:

a. measuring the pH of the scrubber liquor before and after each reaction; or

b. continuously monitoring and recording the pH of the scrubber liquor using equipment that is properly operated and maintained; or

c. when the stoichiometry and operational specifics are known, document the quantity of acid or base charged along with the stoichiometry.

(7) Whenever the monitored value of the pH deviates from the range specified, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. the date and time the deviation began;

b. the magnitude of the deviation at that time;

c. the date(s) the investigation was conducted; and

d. the findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range specified below, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

e. a description of the corrective action;

f. the date it was completed;

g. the date and time the deviation ended;

h. the total period of time (in minutes) during which there was a deviation; and

i. the pH readings immediately after the corrective action.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The permittee shall record and maintain a log or record of operating time for the EU and the scrubber.

(8) Modeling to demonstrate compliance with the Toxic Air Contaminant Statute, ORC 3704.03(F)(4)(b), was not necessary because the EU's maximum annual emissions for each toxic air contaminant, as defined in OAC rule 3745-114-01, will be less than 1 TPY. OAC Chapter 3745-31 requires a permittee to apply for and obtain a new or modified FEPTIO prior to making a modification as defined by OAC rule 3745-31-01. The permittee is hereby advised that changes in the composition of the materials or use of new materials, that would cause the emissions of any toxic air contaminant to increase to above 1 TPY, may require the permittee to apply for and obtain a new FEPTIO.

e) Reporting Requirements

(1) The reports contained in this permit shall be submitted in accordance with the reporting requirements specified in Section A, Standard Terms and Conditions.

(2) In accordance with OAC rule 3745-21-09(B)(4)(c) permittee shall submit quarterly summaries that identify:

a. All three-hour blocks of time when the EU(s) was/were in operation during which the average temperature of the exhaust gases from the condenser was more than 11ºF above the average temperature of the exhaust gases measured during the most recent performance test that demonstrated the EU(s) was/were in compliance;

b. Any records of downtime (date and length of time) for the capture (collection) system, the condenser and/or the monitoring equipment when the EU(s) was/were in operation; and

c. A log of the operating time for the capture system, condenser, monitoring equipment, and EU(s).

These quarterly reports shall be submitted by April 30, July 31, October 31, and January 31, and shall cover the records for the previous calendar quarters.

(3) Any owner or operator of a solvent cleaning operation that is subject to one or more of the VOC-content limitations specified in paragraph (C)(1) of OAC rule 3745-21-23 shall notify the appropriate Ohio EPA DO/LAA of any record maintained in accordance with paragraph (G)(1) of OAC rule 3745-21-23 showing the use of noncomplying solvents. A copy of such record shall be sent to the appropriate Ohio EPA DO/LAA within thirty days following the end of the month in which the use of noncomplying solvents occurs.

(4) The permittee shall submit an annual PER to Ohio EPA by the due date identified in the Authorization section of this permit. The PER shall cover a reporting period of no more than 12 months for each air contaminant source identified in this permit.

(5) The permittee shall identify in the annual PER the following information concerning the operations of the scrubber during the 12-month reporting period for this EU:

a. each period of time when the pH of the scrubber liquor was outside the acceptable range;

b. an identification of any time periods when one of the wet scrubbers was not in service for EUs P048 and P049, when used to minimize or reduce nuisance odors;

c. an identification of each incident of deviation described in e)(5)a. where a prompt investigation was not conducted;

d. an identification of each incident of deviation described in e)(5)a. where prompt corrective action, that would bring the pH into compliance with the acceptable range, was determined to be necessary and was not taken;

e. an identification of each incident of deviation described in e)(5)a. where proper records were not maintained for the investigation and/or the corrective action; and

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 Limitation:

The discharge of VOC emissions into the ambient air from any reactor, distillation operation, crystallizer, centrifuge or vacuum dryer is to be controlled by a surface condenser which has an outlet gas concentration of VOC not exceeding fifty thousand parts per million by volume.

Applicable Compliance Method:

Compliance shall be demonstrated by emissions testing performed in accordance with the methods and procedures specified in f)(2).

b. Emission Limitation:

In accordance with OAC rule 3745-21-23(C)(1), the permittee shall not use a solvent to perform solvent cleaning operations unless the solvent complies with the following applicable VOC-content limitation for medical devices and pharmaceuticals:

i. Product cleaning during manufacturing process

(a) Medical devices and pharmaceuticals: 6.7 lbs/gal as employed.

ii. Repair and maintenance cleaning medical devices and pharmaceuticals:

(a) Tools, equipment and machinery: 6.7 lbs/gal as employed.

(b) General work surfaces: 5.0 lbs/gal as employed.

Applicable Compliance Method:

Compliance shall be demonstrated by the record keeping requirements specified in d)(1).

(2) The permittee shall conduct, or have conducted, emissions testing for this EU per the following requirements:

a. The emission testing shall be conducted within 180 days after initial startup of the EU.

b. The emission testing shall be conducted to demonstrate compliance with the allowable concentration of VOC in the exhaust stream.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emissions rate(s):

Method 25 of 40 CFR Part 60, Appendix A; or

Method 25A of 40 CFR Part 60, Appendix A; and

Alternative U.S. EPA-approved test methods may be used with prior approval from the Ohio EPA.

d. During the emissions testing, the EU shall be operated under operational conditions approved in advance by the appropriate Ohio EPA DO/LAA. Operational conditions that may need to be approved include, but are not limited to, the production rate, the type of material processed, material make-up (solvent content, etc.) or control equipment operational limitations (burner temperature, precipitator voltage, etc.). In general, testing shall be done under *worst case* conditions expected during the life of the permit. As part of the information provided in the Intent to Test (ITT) notification form described below, the permittee shall provide a description of the EU operational conditions they will meet during the emissions testing and describe why they believe *worst case* operating conditions will be met. Prior to conducting the test(s), the permittee shall confirm with the appropriate Ohio EPA DO/LAA that the proposed operating conditions constitute *worst case*. Failure to test under the approved conditions may result in Ohio EPA not accepting the test results as a demonstration of compliance.

e. Not later than 30 days prior to the proposed test date(s), the permittee shall submit an ITT notification to the appropriate Ohio EPA DO/LAA. The ITT notification shall describe in detail the proposed test methods and procedures, the EU operating parameters, the time(s) and date(s) of the test(s) and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Ohio EPA DO/LAA's refusal to accept the results of the emission test(s).

f. Personnel from the appropriate Ohio EPA DO/LAA shall be permitted to witness the test(s), examine the testing equipment and acquire data and information necessary to ensure that the operation of the EU and the testing procedures provide a valid characterization of the emissions from the EU and/or the performance of the control equipment.

g. A comprehensive written report on the results of the emissions test(s) shall be signed by the person(s) responsible for the tests and submitted to the appropriate Ohio EPA DO/LAA within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA DO/LAA.

(3) Formulation data shall be used to determine the VOC contents of the materials employed for each final product and each cleanup material.

g) Miscellaneous Requirements

(1) None.