



Pfizer Inc  
7000 Portage Road  
Kalamazoo, MI 49001-0199

---

**Pfizer Global Supply**

March 23, 2023

EGLE - Air Quality Division  
Grand Rapids District Office  
350 Ottawa Ave NW  
Unit 10  
Grand Rapids, MI 49503

RE: Minor Modification – Rule 216 (2) – Permit to Install No. 43-23

Dear EGLE ROP Team:

Attached, please find the C-001 form, M-001 form, AI-001 form and marked-up Renewable Operating Permit (ROP) required to complete the minor modification to incorporate Permit to Install (PTI) No. 43-23 into the ROP No. MI-ROP-B3610-2021a. The affected emission units are in Section 3 of the ROP.

If you need additional information or have any questions or concerns, please contact Tim Swainston at 269.833.0080 or [Timothy.Swainston@pfizer.com](mailto:Timothy.Swainston@pfizer.com).

Sincerely,

A handwritten signature in blue ink, appearing to read 'David Breen', written over a light blue circular stamp.

**David Breen**  
Site Leader – Kalamazoo

**PGS**  
Global Sterile Injectables

Email and FedEx # 7715 8992 7023

cc/att: Monica Brothers – Email Only



Michigan Department of Environment, Great Lakes, and Energy - Air Quality Division

## RENEWABLE OPERATING PERMIT APPLICATION C-001: CERTIFICATION

*This information is required by Article II, Chapter 1, part 55 (Air Pollution Control) of P.A. 451 of 1994, as amended, and the Federal Clean Air Act of 1990. Failure to provide this information may result in civil and/or criminal penalties. Please type or print clearly.*

**This form is completed and included as part of Renewable Operating Permit (ROP) initial and renewal applications, notifications of change, amendments, modifications, and additional information.**

Form Type C-001	SRN B3610
-----------------	-----------

Stationary Source Name Pharmacia & Upjohn LLC, a subsidiary of Pfizer Inc.	
City Kalamazoo	County Kalamazoo

<b>SUBMITTAL CERTIFICATION INFORMATION</b>	
1. Type of Submittal <i>Check only one box.</i>	
<input type="checkbox"/> Initial Application (Rule 210)	<input checked="" type="checkbox"/> Notification / Administrative Amendment / Modification (Rules 215/216)
<input type="checkbox"/> Renewal (Rule 210)	<input type="checkbox"/> Other, describe on AI-001
2. If this ROP has more than one Section, list the Section(s) that this Certification applies to <u>3</u>	
3. Submittal Media <input checked="" type="checkbox"/> E-mail <input type="checkbox"/> FTP <input type="checkbox"/> Disk <input checked="" type="checkbox"/> Paper	
4. Operator's Additional Information ID - Create an Additional Information (AI) ID that is used to provide supplemental information on AI-001 regarding a submittal. AI <b>-001</b>	

<b>CONTACT INFORMATION</b>	
Contact Name Timothy Swainston	Title Senior EHS Specialist - Environmental
Phone number 269-833-0080	E-mail address timothy.swainston@pfizer.com

<b>This form must be signed and dated by a Responsible Official.</b>				
Responsible Official Name David Breen			Title Site Leader	
Mailing address 7000 Portage Rd.				
City Kalamazoo	State MI	ZIP Code 49001	County Kalamazoo	Country United States
<p><b>As a Responsible Official, I certify that, based on information and belief formed after reasonable inquiry, the statements and information in this submittal are true, accurate and complete.</b></p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"> <div style="width: 60%;"> <hr style="border: 0; border-top: 1px solid black;"/>           Signature of Responsible Official         </div> <div style="width: 35%; text-align: center;"> <div style="font-size: 2em; font-family: cursive; margin-bottom: 5px;">03/23/2023</div> <hr style="border: 0; border-top: 1px solid black;"/>           Date         </div> </div>				



## RENEWABLE OPERATING PERMIT

### M-001: RULE 215 CHANGE NOTIFICATION

### RULE 216 AMENDMENT/MODIFICATION APPLICATION

*This information is required by Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended, and the Federal Clean Air Act of 1990. Failure to obtain a permit required by Part 55 may result in penalties and/or imprisonment.*

1. SRN B3610	2. ROP Number MI-ROP-B3610-2021a	3. County Kalamazoo
4. Stationary Source Name Pharmacia & Upjohn LLC, a subsidiary of Pfizer Inc.		
5. Location Address 7000 Portage Rd.		6. City Kalamazoo
7. Submittal Type - <i>The submittal must meet the criteria for the box checked below. Check only one box. Attach a mark-up of the affected ROP pages for applications for Rule 216 changes.</i> <input type="checkbox"/> <b>Rule 215(1) Notification of change.</b> Complete Items 8 – 10 and 14 <input type="checkbox"/> <b>Rule 215(2) Notification of change.</b> Complete Items 8 – 10 and 14 <input type="checkbox"/> <b>Rule 215(3) Notification of change.</b> Complete Items 8 – 11 and 14 <input type="checkbox"/> <b>Rule 215(5) Notification of change.</b> Complete Items 8 – 10 and 14 <input type="checkbox"/> <b>Rule 216(1)(a)(i)-(iv) Administrative Amendment.</b> Complete Items 8 – 10 and 14 <input type="checkbox"/> <b>Rule 216(1)(a)(v) Administrative Amendment.</b> Complete Items 8 – 14. Results of testing, monitoring & recordkeeping must be submitted. See detailed instructions. <input checked="" type="checkbox"/> <b>Rule 216(2) Minor Modification.</b> Complete Items 8 – 12 and 14 <input type="checkbox"/> <b>Rule 216(3) Significant Modification.</b> Complete Items 8 – 12 and 14, and provide any additional information needed on ROP application forms. See detailed instructions. <input type="checkbox"/> <b>Rule 216(4) State-Only Modification.</b> Complete Items 8 – 12 and 14		
8. Effective date of the change. (MM/DD/YYYY) <i>See detailed instructions.</i> 03/24/2023		9. Change in emissions? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
10. Description of Change - <i>Describe any changes or additions to the ROP, including any changes in emissions and/or pollutants that will occur. If additional space is needed, complete an Additional Information form (AI-001).</i> Incorporate requirements for PTI 43-23. Allow startup of the 1MAV and 2MAV located in B91 and B225.		
11. New Source Review Permit(s) to Install (PTI) associated with this application? If Yes, enter the PTI Number(s) 43-23 - - - - -		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
12. Compliance Status - <i>A narrative compliance plan, including a schedule for compliance, must be submitted using an AI-001 if any of the following are checked No.</i> a. Is the change identified above in compliance with the associated applicable requirement(s)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No b. Will the change identified above continue to be in compliance with the associated applicable requirement(s)? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No c. If the change includes a future applicable requirement(s), will timely compliance be achieved? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
13. Operator's Additional Information ID - <i>Create an Additional Information (AI) ID for the associated AI-001 form used to provide supplemental information.</i>		<b>AI -001</b>
14. Contact Name Timothy Swainston	Telephone No. 269-833-0080	E-mail Address timothy.swainston@pfizer.com
15. This submittal also updates the ROP renewal application submitted on ___/___/___ <input type="checkbox"/> Yes <input checked="" type="checkbox"/> N/A <i>(If yes, a mark-up of the affected pages of the ROP must be attached.)</i>		

**NOTE: A CERTIFICATION FORM (C-001) SIGNED BY A RESPONSIBLE OFFICIAL MUST ACCOMPANY ALL SUBMITTALS**

For Assistance  
Contact: 800-662-9278

www.michigan.gov/egle

EQP 5775 (Rev.04-2019)

Michigan Department of Environment, Great Lakes, and Energy - Air Quality Division



# RENEWABLE OPERATING PERMIT APPLICATION

## AI-001: ADDITIONAL INFORMATION

*This information is required by Article II, Chapter 1, Part 55 (Air Pollution Control) of P.A. 451 of 1994, as amended, and the Federal Clean Air Act of 1990. Failure to obtain a permit required by Part 55 may result in penalties and/or imprisonment. Please type or print clearly. Refer to instructions for additional information to complete this form.*

SRN: B3610	Section Number (if applicable): 3
------------	-----------------------------------

1. Additional Information ID <b>AI-001</b>
---

### Additional Information

2. Is This Information Confidential?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
--------------------------------------	---

Attached are the marked-up pages of ROP No. MI-ROP-B3610-2021a.

## App No. 202300063

## Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

Emission Unit ID	Emission Unit Description (Including Process Equipment & Control Device(s))	Installation Date/ Modification Date	Flexible Group ID
EUCR138-S3	All equipment in or around Building 38 located in (Active Pharmaceutical Ingredients) API Region I. Particulate emissions are controlled by a number of pollution control equipment, including a new W-Rotocloner (038ROTO0214-1).	01-01-1946/ 11-30-2010/ 09-08-2020	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1127-S3	All equipment in or around Building 127 located in API Region I.	01-01-1964/ 11-30-2010	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1155-S3	All equipment in or around Building 155 located in API Region I.	01-01-1966/ 12-11-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1166-S3	All equipment in or around Building 166 located in API Region I.	01-01-1966/ 12-11-1995	FGCRALLPART-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR1195-S3	All equipment in or around Building 195 located in API Region I. (PTI No. 81-15)	01-01-1971/ 12-11-1995/ 06-02-2015	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR244-S3	All equipment in or around Building 44 located in API Region II.	01-01-1938 06-01-1996	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR2149-S3	All equipment in or around Building 149 located in API Region II.	01-01-1965/ 06-01-1996	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR373-S3	All equipment in or around Building 73 located in API Region III. Permit to Install No. 82-16 added Column 10, Tank1830-1, Tank1831-1, and Tank 1832-1 to the emission unit.	01-01-1952/ 06-14-1995 06-28-2016	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR3173-S3	All equipment in or around Building 173, located in KAPI Region III.	01-01-1967/ 06-14-1995/ 08-13-19 07-16-2021	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR3207-S3	All equipment in or around Building 207 located in API Region III.	01-01-1975/ 06-14-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR3225-S3	All equipment in or around Building 225. Located in API Region III.	01-01-1976/ 06-14-1995 03-15-2016 02-07-2019 09-13-2021 01-31-2022 <a href="#">03-24-2023</a>	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3

## Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

Emission Unit ID	Emission Unit Description (Including Process Equipment & Control Device(s))	Installation Date/ Modification Date	Flexible Group ID
EUCR466-S3	All equipment in or around Building 66 located in API Region IV.	01-01-1951/ 12-28-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR476-S3	All equipment in or around Building 76 located in API Region IV.	01-01-1954/ 12-28-1995	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR491COM-S3	All equipment in or around Building 91, commercial area, located in KAPI Region IV.	01-01-1961/ 12-28-1995/ 03-31-2015 08-27-2021 01-31-2022 <a href="#">03-24-2023</a>	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUCR4172-S3	Storage tanks in or around Building 172 located in API Region IV.	01-01-1967/ 12-28-1995	FGCRALLTOX-S3 FGPHARMAMACT-S3 FGCFUG-S3
EUCR4335-S3	All equipment in or around Building 335 located in API Region IV (PTI No. 21-19). Particulate emissions are controlled by a number of pollution control equipment, including a new dust collector (335DUST5000-1).	01-01-1991/ 08-14-1996/ 04-15-2019	FGCRALLPART-S3 FGCRALLTOX-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUC38R6ALL-S3	Equipment in or around building 38, (located in API Region VI), used to manufacture fermentation intermediates and products, which includes the installation of two replacement acetone tanks (ID#TANK1022-1 and TANK1022-2). Emissions from the replacement tanks are controlled by a thermal oxidizer.	01-01-1946/ 11-30-2010/ 10-23-2017/ 05-21-2018/ 9-21-2020	FGCRALLPART-S3 FGCR6FERM-S3 FGCFUG-S3 FGPHARMAMACT-S3 FGCRALLTOX-S3
EUC120R6ALL-S3	Equipment in or around Building 120, part of API region VI, used to manufacture fermentation intermediates and products. Also includes the silos.	01-01-1962/ 07-31-1996	FGCRALLPART-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUC121R6ALL-S3	Equipment in or around Building 121, part of API region VI, used to manufacture fermentation intermediates and products.	01-01-1962/ 07-31-1996/ 10-23-2017 04-30-2018	FGCR6FERM-S3 FGCFUG-S3 FGPHARMAMACT-S3
EUC41MICH33-S3	Exhaust hood in micronizing in B41.	09-01-2006	FGRULE290-S3
EUC76TIS254-S3	UIC surge tank.	01-01-1980	FGRULE290-S3
EUCR1127CENTRIFUGE-S3	Centrifuge.	01-01-2003	FGRULE290-S3
EUCR1127CLEANING-S3	Cleaning station.	01-01-2005	FGRULE290-S3
EUCR1127FILT1268-S3	Sparkler filter.	01-01-2002	FGRULE290-S3
EUCR1155CLEANING-S3	Cleaning station.	01-01-2007	FGRULE290-S3
EUCR1195OT380-S3	Storage tank.	01-01-1971	FGRULE290-S3
EUCR1195SHKRA-S3	Shaker separator.	01-01-1971	FGRULE290-S3

Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

Emission Limits for PM, PM10, and PM2.5							
Exhaust ID	PM, PM10, and PM2.5			PM only			Maximum Gas Flow Rate (dscfm)
	Lbs Per Hour By Size Category*			Lbs Particulate Per 1000 Lbs Of Dry Exhaust Gas			
	A	B	C	A	B	C	
13. EF1C1HB1	0.14	0.1	0.06	0.01	0.01	0.006	2,400
14. SCRB1006	0.82	0.41	0.21	0.01	0.01	0.006	24,000
15. SCRB1007	0.41	0.21	0.1	0.01	0.01	0.006	12,000
16. EX-27	0.33	0.24	0.14	0.01	0.01	0.006	5,500
17. EX-30	0.12	0.09	0.05	0.01	0.01	0.006	2,000
18. EX-34	0.34	0.24	0.15	0.01	0.01	0.006	5,700

\*See Appendix 10-S3 for approved procedures for determination of the particle size category.

**II. MATERIAL LIMITS**

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Material produced in PM-emitting activities	115 lots/month <sup>1</sup>	Calendar month	EUCR3225-S3	SC VI.5	R 336.1225, R 336.1227(2)
2. Lots of product produced in VOC processes.	30 lots/month <sup>2</sup>	Calendar month	EUCR3225-S3	SC VI.7	R 336.1225, R 336.1227(2), R 336.1702(a)
3. <a href="#">Material produced in 1MAV-emitting activities</a>	<a href="#">90 kg/lot</a>	<a href="#">Calendar month</a>	<a href="#">EUCR3225-S3</a>	<a href="#">SC VI.8</a>	<a href="#">R 336.1226(a)</a>
4. <a href="#">Material produced in 2MAV-emitting activities</a>	<a href="#">90kg/lot</a>	<a href="#">Calendar month</a>	<a href="#">EUCR3225-S3</a>	<a href="#">SC VI.9</a>	<a href="#">R 336.1226(a)</a>

**III. PROCESS/OPERATIONAL RESTRICTIONS**

1. The permittee shall not operate equipment located in EUCR3225-S3 in vacuum service while processing a VOC unless the vacuum pump is connected to the thermal oxidizer control and the thermal oxidizer control is installed, maintained, and operated in a satisfactory manner.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a), R 336.1910)
2. The permittee shall capture all waste materials from the solvent cleaning of the solids drum charging glove boxes and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable manner in compliance with all applicable state rules and federal regulations.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))
3. The permittee shall capture all waste materials from the solvent cleaning of the lipid storage tanks and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable manner in compliance with all applicable state rules and federal regulations.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))
4. The permittee shall handle all materials for EUCR3225-S3 activities containing volatile compounds other than water in a manner to minimize the generation of fugitive emissions. The permittee shall keep containers covered at all times except when operator access is necessary.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))

Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
Expiration Date: October 18, 2026  
PTI No: MI-PTI-B3610-2021a

**IV. DESIGN/EQUIPMENT PARAMETER(S)**

NA

**V. TESTING/SAMPLING**

Records shall be maintained on file for a period of five years. (R 336.1213(3)(b)(ii))

NA

**VI. MONITORING/RECORDKEEPING**

Records shall be maintained on file for a period of five years. (R 336.1213(3)(b)(ii))

1. The permittee shall complete all required records in a format acceptable to the AQD District Supervisor and make them available by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition.<sup>2</sup> (R 336.1225, R 336.1702(a), R 336.1331(c), R 336.1910)
2. The permittee shall calculate and record the actual PM, PM10, and PM2.5 emission rates on a monthly basis using a method similar to that described in Appendix 4-S3.<sup>2</sup> (R 336.1225, R 336.1227(2), R 336.1331(c))
3. The permittee shall calculate the actual VOC emissions from each process for unconnected VOC equipment while emitting from the unconnected bypass vent of T-K271 for each calendar month using the method detailed in Appendix 4-S3.<sup>2</sup> (R 336.1702(a))
4. The permittee shall conduct and record the results of a visible emission observation (described in Appendix 3-S3) of the particulate control device exhausts once per calendar month during a period when the particulate control devices are being operated.<sup>2</sup> (R 336.1331)
5. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in PM-emitting activities in EUCR3225-S3 on a calendar month basis.<sup>1</sup> (R 336.1225, R 336.1227(2))
6. The permittee shall calculate the actual VOC emissions from the silica slurry exhaust hood for each calendar month and 12-month rolling time period, as determined at the end of each calendar month, in a format acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and shall make them available to the department upon request.<sup>2</sup> (R 336.1702(a))
7. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in lots, produced in VOC-emitting activities in EUCR3225-S3 on a calendar month basis.<sup>1</sup> (R 336.1225, R 336.1227(2))
- ~~7-8. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in kg/lot, produced in 1MAV-emitting activities in EUCR3225-S3 on a calendar month basis. (R 336.1226(a))~~
- ~~9. The permittee shall monitor and record, in a satisfactory manner, the amount of material, in kg/lot, produced in 2MAV-emitting activities in EUCR3225-S3 on a calendar month basis. (R 336.1226(a))~~

See Appendix 4-S3

**VII. REPORTING**

1. Prompt reporting of deviations pursuant to General Conditions 21 and 22 of Part A. (R 336.1213(3)(c)(ii))
2. Semiannual reporting of monitoring and deviations pursuant to General Condition 23 of Part A. The report shall be postmarked or received by the appropriate AQD District Office by March 15 for reporting period July 1 to December 31 and September 15 for reporting period January 1 to June 30. (R 336.1213(3)(c)(i))

**Formatted:** Font: Not Bold

**Formatted:** Indent: Left: 0.25", No bullets or numbering, Tab stops: Not at 0.25"

**Formatted:** Font: Bold

**Commented [ST1]:** Condition VII.1 in PTI 43-23 is no longer applicable as the letter to the district office was submitted at the same time as the ROP modification request.

## Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

**VIII. STACK/VENT RESTRICTIONS**

The exhaust gases from the stacks listed in the table below shall be discharged unobstructed vertically upwards to the ambient air unless otherwise noted:

Stack & Vent ID	Maximum Exhaust Dimensions (inches)	Minimum Height Above Ground (feet)	Underlying Applicable Requirements
1. SVC225EF1C1HB1	14 <sup>2</sup>	55 <sup>2</sup>	R 336.1225, 40 CFR 52.21(c) and (d)
2. SVC225EX27	29 <sup>2</sup>	68 <sup>2</sup>	R 336.1225, 40 CFR 52.21(c) and (d)
3. SVC225EX30	17 <sup>2</sup>	54 <sup>2</sup>	R 336.1225, 40 CFR 52.21(c) and (d)
4. SVC225EX34	25 <sup>2</sup>	53 <sup>2</sup>	R 336.1225, 40 CFR 52.21(c) and (d)
5. SVC225SCRB1006	35 <sup>2</sup>	79 <sup>2</sup>	R 336.1225, 40 CFR 52.21(c) and (d)
6. SVC225SCRB1007	25 <sup>2</sup>	80 <sup>2</sup>	R 336.1225, 40 CFR 52.21(c) and (d)
7. SVC225TK271	4 <sup>1</sup>	61 <sup>1</sup>	R 336.1225 40 CFR 52.21(c) and (d)

**IX. OTHER REQUIREMENT(S)**

- The permittee shall comply with all applicable provisions of the National Emission Standards for Hazardous Air Pollutants, as specified in 40 CFR Part 63, Subpart A and Subpart GGG for Pharmaceuticals Production by the initial compliance date.<sup>2</sup> (40 CFR Part 63, Subparts A and GGG)

**Footnotes:**

<sup>1</sup>This condition is state only enforceable and was established pursuant to Rule 201(1)(b).

<sup>2</sup>This condition is federally enforceable and was established pursuant to Rule 201(1)(a).

Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

**EUCR491COM-S3  
 EMISSION UNIT CONDITIONS**

**DESCRIPTION**

All equipment in or around Building 91, commercial area, located in API Region IV.

**Flexible Group ID:** FGCRALLPART-S3, FGCRALLTOX-S3, FGCFUG-S3, FGPHARMAMACT-S3

**POLLUTION CONTROL EQUIPMENT**

HEPA Filters on DUST1010, EX27 filters 1049 and 1056, EX117, EX118, EX119, Exhaust Fans on EX107, EX124; Condensers, connected to TOX; Scrubbers, connected to TOX.

**I. EMISSION LIMITS**

Pollutant	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. VOC	50 lbs- <del>per-month</del> <sup>1</sup>	<del>Per</del> Calendar month	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
2. VOC	10 lbs- <del>per-lot</del> <sup>1</sup>	<del>Per</del> Each lot	Unconnected VOC processes	SC VI.3	R 336.1225, R 336.1227(2)
3. Methanol	0.1 pph <sup>1</sup>	Hourly	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
4. Methylene Chloride	1 pph <sup>1</sup>	Hourly	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
5. Ozone	0.2 pph <sup>1</sup>	Hourly	TANK1615 not controlled by the thermal oxidizer	SC VI.3	R 336.1225, R 336.1227(2)
6. Particulate	90 lbs- <del>per-month</del> <sup>1</sup>	<del>Per</del> Calendar month	All process vents combined	SC VI.2	R 336.1225, R 336.1227(2)
7. Particulate	Limits in the table below: <sup>2</sup>	Hourly	EUCR491COM-S3	SC VI.2	R 336.1225, R 336.1331(c)

Exhaust ID	Lbs Particulate Per Hour By Size Category+			Lbs Particulate Per 1000 Lbs Of Dry Exhaust Gas			Maximum Gas Flow Rate  (dscfm)
	A	B	C	A	B	C	
8. DUST1010	0.19	0.13	0.08	0.01	0.01	0.006	3,090
9. EX-27	0.23	0.17	0.10	0.01	0.01	0.006	4,000
10. EX-107	-	1.44	0.86	-	0.10	0.06	3,360
11. EX-117	0.06	0.043	0.026	0.01	0.01	0.006	1,000
12. EX-118	0.06	0.043	0.026	0.01	0.01	0.006	1,000
13. EX-119	0.06	0.043	0.026	0.01	0.01	0.006	1,000
14. EX-124	-	1.37	0.82	-	0.10	0.06	3,200

+ See Appendix 10-S3 for approved procedures for determination of the particle size category.

## Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

**II. MATERIAL LIMITS**

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Lots of product produced in TSP processes.	30 lots-per month <sup>1</sup>	PerCalendar month	EUCR491COM-S3	SC VI.65	R 336.1225, R 336.1227(2)
2. Lots of VOC emitting product produced in equipment not controlled by the thermal oxidizer	5 lots-per month <sup>1</sup>	PerCalendar month	EUCR491COM-S3	SC VI.67	R 336.1225, R 336.1227(2)
3. <a href="#">Material produced in 1MAV-emitting activities</a>	90 kg/lot	Per month	<a href="#">EUCR491COM-S3</a>	<a href="#">SC VI.7</a>	<a href="#">R 335.1226(a)</a>

**III. PROCESS/OPERATIONAL RESTRICTIONS**

1. The permittee shall not operate equipment located in EUCR491COM-S3 in vacuum service, while processing a VOC, unless a vacuum pump connected to the thermal oxidizer control is installed, maintained, and operated in a satisfactory manner acceptable to the AQD District Supervisor.<sup>2</sup> (R 336.1224, R 336.1910)
2. The permittee shall capture all waste materials from the solvent cleaning of the lipid storage tanks and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable manner in compliance with all applicable state rules and federal regulations.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))
3. The permittee shall handle all materials for EUCR491COM-S3 activities containing volatile compounds other than water in a manner to minimize the generation of fugitive emissions. The permittee shall keep containers covered at all times except when operator access is necessary.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))

**IV. DESIGN/EQUIPMENT PARAMETER(S)**

NA

**V. TESTING/SAMPLING**

Records shall be maintained on file for a period of five years. (R 336.1213(3)(b)(ii))

NA

**VI. MONITORING/RECORDKEEPING**

Records shall be maintained on file for a period of five years. (R 336.1213(3)(b)(ii))

1. The permittee shall complete all required calculations in a format acceptable to the AQD District Supervisor by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition.<sup>2</sup> (R 336.1225, [R 336.1702\(a\)](#)~~R-336.4227(2)~~, R 336.1331(c), [R 336.1910702\(a\)](#))
2. The permittee shall calculate and record the actual particulate emission rates on a monthly basis using a method similar to that described in Appendix 4-S3.<sup>2</sup> (R 336.1225, R 336.1227(2), R 336.1331(c))
3. The permittee shall calculate the actual VOC emissions from each process for unconnected VOC equipment for each calendar month using the method detailed in Appendix 4-S3.<sup>2</sup> (R 336.1702(a))

## Section 3 – Active Pharmaceutical Ingredients (API)

ROP No: MI-ROP-B3610-2021a  
 Expiration Date: October 18, 2026  
 PTI No: MI-PTI-B3610-2021a

**II. MATERIAL LIMITS**

Material	Limit	Time Period/ Operating Scenario	Equipment	Monitoring/ Testing Method	Underlying Applicable Requirements
1. Lots of product produced in TSP processes.	30 lots-per month <sup>1</sup>	PerCalendar month	EUCR491COM-S3	SC VI.65	R 336.1225, R 336.1227(2)
2. Lots of VOC emitting product produced in equipment not controlled by the thermal oxidizer	5 lots-per month <sup>1</sup>	PerCalendar month	EUCR491COM-S3	SC VI.67	R 336.1225, R 336.1227(2)
3. Material produced in 1MAV-emitting activities	90 kg/lot	Per month	EUCR491COM-S3	SC VI.7	R 335.1226(a)

**III. PROCESS/OPERATIONAL RESTRICTIONS**

- The permittee shall not operate equipment located in EUCR491COM-S3 in vacuum service, while processing a VOC, unless a vacuum pump connected to the thermal oxidizer control is installed, maintained, and operated in a satisfactory manner acceptable to the AQD District Supervisor.<sup>2</sup> (R 336.1224, R 336.1910)
- The permittee shall capture all waste materials from the solvent cleaning of the lipid storage tanks and shall store them in closed containers. The permittee shall dispose of all these materials in an acceptable manner in compliance with all applicable state rules and federal regulations.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))
- The permittee shall handle all materials for EUCR491COM-S3 activities containing volatile compounds other than water in a manner to minimize the generation of fugitive emissions. The permittee shall keep containers covered at all times except when operator access is necessary.<sup>2</sup> (R 336.1224, R 336.1225, R 336.1702(a))

**IV. DESIGN/EQUIPMENT PARAMETER(S)**

NA

**V. TESTING/SAMPLING**

Records shall be maintained on file for a period of five years. (R 336.1213(3)(b)(ii))

NA

**VI. MONITORING/RECORDKEEPING**

Records shall be maintained on file for a period of five years. (R 336.1213(3)(b)(ii))

- The permittee shall complete all required calculations in a format acceptable to the AQD District Supervisor by the last day of the calendar month, for the previous calendar month, unless otherwise specified in any monitoring/recordkeeping special condition.<sup>2</sup> (R 336.1225, R 336.1702(a), R 336.1227(2), R 336.1331(c), R 336.1910702(a))
- The permittee shall calculate and record the actual particulate emission rates on a monthly basis using a method similar to that described in Appendix 4-S3.<sup>2</sup> (R 336.1225, R 336.1227(2), R 336.1331(c))
- The permittee shall calculate the actual VOC emissions from each process for unconnected VOC equipment for each calendar month using the method detailed in Appendix 4-S3.<sup>2</sup> (R 336.1702(a))