

**MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY  
AIR QUALITY DIVISION**

August 8, 2024

**PERMIT TO INSTALL**  
98-24

**ISSUED TO**  
Pharmacia & Upjohn Company, LLC, A Subsidiary of Pfizer Inc

**LOCATED AT**  
7000 Portage Road  
Kalamazoo, Michigan 49001

**IN THE COUNTY OF**  
Kalamazoo

**STATE REGISTRATION NUMBER**  
B3610

The Air Quality Division has approved this Permit to Install, pursuant to the delegation of authority from the Michigan Department of Environment, Great Lakes, and Energy. This permit is hereby issued in accordance with and subject to Section 5505(1) of Article II, Chapter I, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended. Pursuant to Air Pollution Control Rule 336.1201(1), this permit constitutes the permittee's authority to install the identified emission unit(s) in accordance with all administrative rules of the Department and the attached conditions. Operation of the emission unit(s) identified in this Permit to Install is allowed pursuant to Rule 336.1201(6).

DATE OF RECEIPT OF ALL INFORMATION REQUIRED BY RULE 203: <b>April 2, 2024</b>	
DATE PERMIT TO INSTALL APPROVED: <b>August 8, 2024</b>	SIGNATURE:
DATE PERMIT VOIDED:	SIGNATURE:
DATE PERMIT REVOKED:	SIGNATURE:

## PERMIT TO INSTALL

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## COMMON ACRONYMS

AQD	Air Quality Division
BACT	Best Available Control Technology
CAA	Clean Air Act
CAM	Compliance Assurance Monitoring
CEMS	Continuous Emission Monitoring System
CFR	Code of Federal Regulations
COMS	Continuous Opacity Monitoring System
Department/department/EGLE	Michigan Department of Environment, Great Lakes, and Energy
EU	Emission Unit
FG	Flexible Group
GACS	Gallons of Applied Coating Solids
GC	General Condition
GHGs	Greenhouse Gases
HVLP	High Volume Low Pressure*
ID	Identification
IRSL	Initial Risk Screening Level
ITSL	Initial Threshold Screening Level
LAER	Lowest Achievable Emission Rate
MACT	Maximum Achievable Control Technology
MAERS	Michigan Air Emissions Reporting System
MAP	Malfunction Abatement Plan
MSDS	Material Safety Data Sheet
NA	Not Applicable
NAAQS	National Ambient Air Quality Standards
NESHAP	National Emission Standard for Hazardous Air Pollutants
NSPS	New Source Performance Standards
NSR	New Source Review
PS	Performance Specification
PSD	Prevention of Significant Deterioration
PTE	Permanent Total Enclosure
PTI	Permit to Install
RACT	Reasonable Available Control Technology
ROP	Renewable Operating Permit
SC	Special Condition
SCR	Selective Catalytic Reduction
SNCR	Selective Non-Catalytic Reduction
SRN	State Registration Number
TBD	To Be Determined
TEQ	Toxicity Equivalence Quotient
USEPA/EPA	United States Environmental Protection Agency
VE	Visible Emissions

\*For HVLP applicators, the pressure measured at the gun air cap shall not exceed 10 psig.

## POLLUTANT / MEASUREMENT ABBREVIATIONS

acfm	Actual cubic feet per minute
BTU	British Thermal Unit
°C	Degrees Celsius
CO	Carbon Monoxide
CO <sub>2</sub> e	Carbon Dioxide Equivalent
dscf	Dry standard cubic foot
dscm	Dry standard cubic meter
°F	Degrees Fahrenheit
gr	Grains
HAP	Hazardous Air Pollutant
Hg	Mercury
hr	Hour
HP	Horsepower
H <sub>2</sub> S	Hydrogen Sulfide
kW	Kilowatt
lb	Pound
m	Meter
mg	Milligram
mm	Millimeter
MM	Million
MW	Megawatts
NMOC	Non-Methane Organic Compounds
NO <sub>x</sub>	Oxides of Nitrogen
ng	Nanogram
PM	Particulate Matter
PM <sub>10</sub>	Particulate Matter equal to or less than 10 microns in diameter
PM <sub>2.5</sub>	Particulate Matter equal to or less than 2.5 microns in diameter
pph	Pounds per hour
ppm	Parts per million
ppmv	Parts per million by volume
ppmw	Parts per million by weight
psia	Pounds per square inch absolute
psig	Pounds per square inch gauge
scf	Standard cubic feet
sec	Seconds
SO <sub>2</sub>	Sulfur Dioxide
TAC	Toxic Air Contaminant
Temp	Temperature
THC	Total Hydrocarbons
tpy	Tons per year
µg	Microgram
µm	Micrometer or Micron
VOC	Volatile Organic Compounds
yr	Year

## GENERAL CONDITIONS

1. The process or process equipment covered by this permit shall not be reconstructed, relocated, or modified, unless a Permit to Install authorizing such action is issued by the Department, except to the extent such action is exempt from the Permit to Install requirements by any applicable rule. **(R 336.1201(1))**
2. If the installation, construction, reconstruction, relocation, or modification of the equipment for which this permit has been approved has not commenced within 18 months, or has been interrupted for 18 months, this permit shall become void unless otherwise authorized by the Department. Furthermore, the permittee or the designated authorized agent shall notify the Department via the Supervisor, Permit Section, Air Quality Division, Michigan Department of Environment, Great Lakes, and Energy, P.O. Box 30260, Lansing, Michigan 48909-7760, if it is decided not to pursue the installation, construction, reconstruction, relocation, or modification of the equipment allowed by this Permit to Install. **(R 336.1201(4))**
3. If this Permit to Install is issued for a process or process equipment located at a stationary source that is not subject to the Renewable Operating Permit program requirements pursuant to Rule 210 (R 336.1210), operation of the process or process equipment is allowed by this permit if the equipment performs in accordance with the terms and conditions of this Permit to Install. **(R 336.1201(6)(b))**
4. The Department may, after notice and opportunity for a hearing, revoke this Permit to Install if evidence indicates the process or process equipment is not performing in accordance with the terms and conditions of this permit or is violating the Department's rules or the Clean Air Act. **(R 336.1201(8), Section 5510 of Act 451, PA 1994)**
5. The terms and conditions of this Permit to Install shall apply to any person or legal entity that now or hereafter owns or operates the process or process equipment at the location authorized by this Permit to Install. If the new owner or operator submits a written request to the Department pursuant to Rule 219 and the Department approves the request, this permit will be amended to reflect the change of ownership or operational control. The request must include all of the information required by subrules (1)(a), (b), and (c) of Rule 219 and shall be sent to the District Supervisor, Air Quality Division, Michigan Department of Environment, Great Lakes, and Energy. **(R 336.1219)**
6. Operation of this equipment shall not result in the emission of an air contaminant which causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property, or which causes unreasonable interference with the comfortable enjoyment of life and property. **(R 336.1901)**
7. The permittee shall provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of a hazardous or toxic air pollutant which continue for more than one hour in excess of any applicable standard or limitation, or emissions of any air contaminant continuing for more than two hours in excess of an applicable standard or limitation, as required in Rule 912, to the Department. The notice shall be provided not later than two business days after start-up, shutdown, or discovery of the abnormal condition or malfunction. Written reports, if required, must be filed with the Department within 10 days after the start-up or shutdown occurred, within 10 days after the abnormal conditions or malfunction has been corrected, or within 30 days of discovery of the abnormal condition or malfunction, whichever is first. The written reports shall include all of the information required in Rule 912(5). **(R 336.1912)**
8. Approval of this permit does not exempt the permittee from complying with any future applicable requirements which may be promulgated under Part 55 of 1994 PA 451, as amended or the Federal Clean Air Act.
9. Approval of this permit does not obviate the necessity of obtaining such permits or approvals from other units of government as required by law.
10. Operation of this equipment may be subject to other requirements of Part 55 of 1994 PA 451, as amended and the rules promulgated thereunder.

11. Except as provided in subrules (2) and (3) or unless the special conditions of the Permit to Install include an alternate opacity limit established pursuant to subrule (4) of Rule 301, the permittee shall not cause or permit to be discharged into the outer air from a process or process equipment a visible emission of density greater than the most stringent of the following. The grading of visible emissions shall be determined in accordance with Rule 303 (R 336.1303). **(R 336.1301)**
  - a) A six-minute average of 20 percent opacity, except for one six-minute average per hour of not more than 27 percent opacity.
  - b) A visible emission limit specified by an applicable federal new source performance standard.
  - c) A visible emission limit specified as a condition of this Permit to Install.
12. Collected air contaminants shall be removed as necessary to maintain the equipment at the required operating efficiency. The collection and disposal of air contaminants shall be performed in a manner so as to minimize the introduction of contaminants to the outer air. Transport of collected air contaminants in Priority I and II areas requires the use of material handling methods specified in Rule 370(2). **(R 336.1370)**
13. The Department may require the permittee to conduct acceptable performance tests, at the permittee's expense, in accordance with Rule 1001 and Rule 1003, under any of the conditions listed in Rule 1001. **(R 336.2001)**

## EMISSION UNIT SPECIAL CONDITIONS

### EMISSION UNIT SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Emission Unit ID	Emission Unit Description (Including Process Equipment & Control Device(s))	Installation Date / Modification Date	Flexible Group ID
EUC38R6ALL-S3	Equipment in or around building 38, part of Region VI, used to manufacture fermentation intermediates and products.	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
EUC121R6ALL-S3	Equipment in or around Building 121, part of KAPI region VI, used to manufacture fermentation intermediates and products.	01-01-1962/ 07-31-1996/ 10-23-2017/ 04-30-2018	FGCR6FERM-3 FGCFUG-S3 FGPHARMAMACT-S3

Changes to the equipment described in this table are subject to the requirements of R 336.1201, except as allowed by R 336.1278 to R 336.1291.

## FLEXIBLE GROUP SPECIAL CONDITIONS

### FLEXIBLE GROUP SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

<b>Flexible Group ID</b>	<b>Flexible Group Description</b>	<b>Associated Emission Unit IDs</b>
FGCR6FERM-S3	Fermentation processes common to Buildings 38 and 121	EUC38R6ALL-S3 EUC121R6ALL-S3

**FGCR6FERM-S3  
 FLEXIBLE GROUP CONDITIONS**

**DESCRIPTION**

Fermentation processes common to Buildings 38 and 121.

**Emission Unit:** EUC38R6ALL-S3, EUC121R6ALL-S3

**POLLUTION CONTROL EQUIPMENT**

NA

**I. EMISSION LIMIT(S)**

<b>Pollutant</b>	<b>Limit</b>	<b>Time Period / Operating Scenario</b>	<b>Equipment</b>	<b>Monitoring / Testing Method</b>	<b>Underlying Applicable Requirements</b>
1. VOC and acetone	34.5 tpy	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3 operations other than KCF production	SC VI.2	R 336.1224, R 336.1702(a)
2. VOC	45.7 tpy	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.3	R 336.1205(3) R 336.1702(a)
3. VOC	24.0 tons	Calendar months April through September of each calendar year, as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.4	40 CFR 52.21(d)
4. Acetaldehyde	9.6 tons per year <sup>1</sup>	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.5	R 336.1225(3)
5. Formaldehyde	1.9 tons per year <sup>1</sup>	12-month rolling time period as determined at the end of each calendar month	FGCR6FERM-S3	SC VI.5	R 336.1225(3)

**II. MATERIAL LIMIT(S)**

1. The permittee shall not produce more than 14 lots of product code KCF in EUC121R6ALL-S3 per year, based on a 12-month rolling time period as determined at the end of each calendar month. **(R 336.1205(3), R 336.1702(a))**

**III. PROCESS/OPERATIONAL RESTRICTION(S)**

1. The permittee shall not exceed a maximum aeration rate of 150,000 standard cubic feet per minute supplied to all fermentation vessels combined. **(R 336.2902)**
2. The permittee shall limit concurrent operations in FGCR6FERM-S3 as follows:<sup>1</sup>
  - a) No more than 13 fermentation operations for product code NM shall occur at the same time.

- b) No more than 4 fermentation operations for product code AX or product code 1DF shall occur at the same time.
- c) No more than 4 fermentation operations for product code KCF shall occur at the same time.

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

NA

#### **V. TESTING/SAMPLING**

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

NA

#### **VI. MONITORING/RECORDKEEPING**

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

1. The permittee shall continuously monitor and record, in a satisfactory manner, the aeration rate supplied to all fermentation vessels combined during operation of FGCR6FERM-S3. Aeration rate data must complete and record a minimum of one cycle of operation (sampling and data recording) for each successive 15-minute period during aeration and the maximum aeration rate shall be recorded once each calendar month that aeration occurs. **(R 336.1205)**
2. To demonstrate compliance with SC I.1, the permittee shall calculate the VOC and acetone emission rate from FGCR6FERM-S3 operations other than KCF production monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1702(a))**
3. To demonstrate compliance with SC I.2, the permittee shall calculate the VOC emission rate from all FGCR6FERM-S3 operations monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1205(3), R 336.1702(a))**
4. The permittee shall calculate the cumulative VOC emissions from FGCR6FERM-S3 monthly, for calendar months April through September of each calendar year, using a method acceptable to the AQD District Supervisor. The calculated emission total from a calendar year shall not carry forward to the next calendar year; the calculated emission total shall begin at zero each calendar year. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(40 CFR 52.21(d))**
5. The permittee shall calculate the acetaldehyde and formaldehyde emission rates from FGCR6FERM-S3 monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor. The permittee shall keep all records on file at the facility and make them available to the Department upon request.<sup>1</sup> **(R 336.1225(3))**
6. To demonstrate compliance with SC III.2, the permittee shall keep the following records:<sup>1</sup> **(R 336.1225)**
  - a) The number of fermentation operations for product NM that occur during each calendar day.
  - b) The number of fermentation operations for product AX and for product 1DF that occur during each calendar day.
  - c) The number of fermentation operations for product KCF that occur during each calendar day.
7. The permittee shall keep a record for each lot of KCF produced in FGCR6FERM-S3, identifying the vessel and building in which the lot was produced.<sup>1</sup> **(R 336.1225)**
8. The permittee shall record the number of lots of product code KCF produced in EUC121R6ALL-S3 monthly, for the preceding 12-month rolling time period, using a method acceptable to the AQD District Supervisor.

The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1205(3))**

**VII. REPORTING**

1. The permittee shall notify the Department if a change in land use occurs for property classified as industrial or as a public roadway, where this classification was relied upon to demonstrate compliance with Rule 225(1). The permittee shall submit the notification to the AQD District Supervisor, within 30 days of the actual land use change. Within 60 days of the land use change, the permittee shall submit to the AQD District Supervisor a plan for complying with the requirements of Rule 225(1). The plan shall require compliance with Rule 225(1) no later than one year after the due date of the plan submittal.<sup>1</sup> **(R 336.1225(4))**

**VIII. STACK/VENT RESTRICTION(S)**

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

<b>Stack &amp; Vent ID</b>	<b>Maximum Exhaust Diameter / Dimensions (inches)</b>	<b>Minimum Height Above Ground (feet)</b>	<b>Underlying Applicable Requirements</b>
1. SV-F56	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
2. SV-F54	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
3. SV-52	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
4. SV-F50	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
5. SV-F48	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
6. SV-F46	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
7. SV-F55	40.4	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
8. SV-F53	40.4	82.6	R 336.1225, 40 CFR 52.21(c) and (d)
9. SV-F51	19.5	82.6	R 336.1225, 40 CFR 52.21(c) and (d)
10. SV-F47	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
11. SV-F45	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
12. SV-F33	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
13. SV-F34	40.4	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
14. SV-35	40.4	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
15. SV-F36	40.4	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
16. SV-F37	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
17. SV-F38	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)

<b>Stack &amp; Vent ID</b>	<b>Maximum Exhaust Diameter / Dimensions (inches)</b>	<b>Minimum Height Above Ground (feet)</b>	<b>Underlying Applicable Requirements</b>
18. SV-F39	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)
19. SV-F40	19.5	72.6	R 336.1225, 40 CFR 52.21(c) and (d)

**IX. OTHER REQUIREMENT(S)**

NA

**Footnotes:**

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