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

October 10, 2023

PERMIT TO INSTALL 102-23A

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:

September 22, 2023

DATE PERMIT TO INSTALL APPROVED: October 10, 2023	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
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POLLUTANT / MEASUREMENT ABBREVIATIONS

BTU British Thermal Unit	
°C Degrees Celsius	
CO Carbon Monoxide	
CO ₂ 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 ₂ S Hydrogen Sulfide	
kW Kilowatt	
lb Pound	
m Meter	
mg Milligram	
mm Millimeter	
MM Million	
MW Megawatts	
NMOC Non-Methane Organic Compounds	
NO _x Oxides of Nitrogen	
ng Nanogram	
PM Particulate Matter	
PM10 Particulate Matter equal to or less than 10 microns in diamet	
PM2.5 Particulate Matter equal to or less than 2.5 microns in diame	ter
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 ₂ 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))
- 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 condition 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.

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- 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)
- 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
EUB91CPL-S3	All equipment used in the Commercial	8-24-2023 /	NA
	Product Laboratory in Building 91.	10-10-2023	

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.

EUB91CPL-S3 EMISSION UNIT CONDITIONS

DESCRIPTION

All equipment used in the Commercial Product Laboratory in Building 91.

POLLUTION CONTROL EQUIPMENT

NA

I. EMISSION LIMIT(S)

Pollutant	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. Aggregate HAPs ¹	0.99 tpy	12-month rolling time period	EUB91CPL-S3	VI.4	R 336.1225
2. VOCs	1.98 tpy	12-month rolling time period	EUB91CPL-S3	VI.3	R 336.1225 R 336.1702
3. Bis- (trimethylsilyl)- trifluoroacetamide (CAS # 25561-30- 2) ¹	0.87 tpy	12-month rolling time period	EUB91CPL-S3	VI.5	R 336.1224 R 336.1225
4. Particulate Matter (PM)	0.10 pounds per 1,000 pounds of exhaust gas calculated on a dry gas basis	Test Protocol	EUB91CPL-S3	V.1	R 336.1331
5. Each Particulate TAC ¹	0.14 pph	Test Protocol	EUB91CPL-S3	V.1	R 336.1225
6. Each Particulate TAC ¹	10 pounds per month	Monthly	EUB91CPL-S3	VI.6	R 336.1225
7. Opacity	10%	6-Minute Average	All stacks individually in EUB91CPL-S3	VI.7	R 336.1301
8. Estradiol & estradiol hemihydrate combined ¹	0.23 pounds per year	12-month rolling time period	EUB91CPL-S3	VI.8	R.336.1225

II. MATERIAL LIMIT(S)

NA

III. PROCESS/OPERATIONAL RESTRICTION(S)

1. The permittee shall not operate more than two work areas in EUB91CPL-S3 at any given time. (R 336.1225, R 336.1702)

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))

1. Upon request of the AQD District Supervisor, the permittee shall verify the PM, and/or the particulate TAC emission rates from EUB91CPL-S3, by testing at the owner's expense and in accordance with Department requirements. Testing shall be performed using an approved EPA Method listed in:

Pollutant	Test Method Reference		
PM	40 CFR Part 60, Appendix A; Part 10 of the Michigan Air Pollution Control Rules		
Particulate TACs	40 CFR Part 60, Appendix A; 40 CFR Part 61, Appendix B; 40 CFR Part 63, Appendix A		

An alternate method, or a modification to the approved EPA Method, may be specified in an AQD-approved Test Protocol. No less than 30 days prior to testing, the permittee shall submit a complete test plan to the AQD Technical Programs Unit and District Office. The permittee shall submit a complete report of the test results to the AQD Technical Programs Unit and District Office within 60 days following the last date of the test. (R 336.2001, R 336.2003, R 336.2004, 40 CFR 52.21(c) and (d))

VI. MONITORING/RECORDKEEPING

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

- 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. (R 336.1224, R 336.1225, R 336.1702(a), 40 CFR 52.21(c) & (d))
- The permittee shall maintain a current listing from the manufacturer of the chemical composition of each material used in EUB91CPL-S3 including the weight percent of each component. The data may consist of Material Safety Data Sheets, manufacturer's formulation data, or both as deemed acceptable by the AQD District Supervisor. The permittee shall keep all records on file and make them available to the Department upon request.¹ (R 336.1224, R 336.1225)
- 3. The permittee shall calculate the VOC emission rate from EUB91CPL-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 336.1702(a))**
- 4. The permittee shall calculate the aggregate HAP emission rate from EUB91CPL-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.¹ (R 336.1225)
- The permittee shall calculate the Bis-(trimethylsilyl)-trifluoroacetamide (CAS # 25561-30-2) emission rate from EUB91CPL-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 request¹ (R 336.1224, R 336.1225)
- 6. The permittee shall calculate emission rate of each particulate TAC from EUB91CPL-S3 on a monthly basis 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.¹ (R 336.1225)
- The permittee shall conduct and record the results of visible emission observations (described in Appendix 3-S3 of MI-ROP-B3610-2021a) for all stacks individually in EUB91CPL-S3. The readings shall be performed once per calendar month during a period when EUB91CPL-S3 is being operated. (R 336.1301)

 The permittee shall calculate the estradiol and estradiol hemihydrate emission rates from EUB91CPL-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 request¹ (R 336.1225)

VII. <u>REPORTING</u>

NA

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:

	Stack & Vent ID	Maximum Exhaust Diameter / Dimensions (inches)	Minimum Height Above Ground (feet)	Underlying Applicable Requirements
1.	SV091FANE1860-1	72	55	R 336.1225 40 CFR 52.21 (c) & (d)
2.	SV091FANE1860-2	72	55	R 336.1225, 40 CFR 52.21 (c) & (d)
3.	SV091FANE1860-3	72	55	R 336.1225, 40 CFR 52.21 (c) & (d)

IX. OTHER REQUIREMENT(S)

NA

Footnotes:

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