

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

September 30, 2021

**PERMIT TO INSTALL  
73-21**

**ISSUED TO  
PAR Sterile Products, LLC**

**LOCATED AT  
870 Parkdale Road  
Rochester, Michigan 48307**

**IN THE COUNTY OF  
Oakland**

**STATE REGISTRATION NUMBER  
B2329**

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>July 28, 2021</b>	
DATE PERMIT TO INSTALL APPROVED: <b>September 30, 2021</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
PM10	Particulate Matter equal to or less than 10 microns in diameter
PM2.5	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 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.

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
EU-103-PACKAGE	Isopropyl alcohol (IPA) use in packaging operations	1/1/1980 7/12/2000	FG-IPA-USE
EU-104-PREP	Isopropyl alcohol (IPA) use in preparation services	1/1/1980 7/12/2000	FG-IPA-USE
EU-114-WIPEUP	Isopropyl alcohol (IPA) use in IPA wipe-up	1/1/1980 7/12/2000	FG-IPA-USE
EULABDIESELGEN	Cummings Model DFEK, 755 HP (500 kW kilowatts (kW)) diesel-fueled emergency engine with a model year of 2011 or later, and a displacement of <10 liters/cylinder.	10/01/2013	FGEMERGENS
EUDIESELGEN	Kohler, 1744 HP (1300 kW kilowatts (kW)) diesel-fueled emergency engine with a model year of 2011 or later, and a displacement of <10 liters/cylinder.	10/2018	FGEMERGENS

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>
FGEMERGENS	Two Diesel fired emergency generators.	EULABDIESELGEN, EUDIESELGEN
FG-IPA-USE	Flexible group which includes all IPA use throughout the facility for cleaning and disinfecting process equipment and removing labels from containers.	EU-103-PACKAGE, EU-104-PREP, EU-114-WIPEUP

**FGEMERGENS  
 FLEXIBLE GROUP CONDITIONS**

**DESCRIPTION**

Two Diesel fired emergency generators.

**Emission Unit:** EULABDIESELGEN, EUDIESELGEN

**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. NMHC + NO <sub>x</sub>	6.4 g/kW-hr	Hourly	Each engine within FGEMERGENS	SC.V.1, SC.VI.2	40 CFR 60.4205(a), Table 1 of 40 CFR Part 60, Subpart IIII
2. CO	3.5 g/kW-hr	Hourly	Each engine within FGEMERGENS	SC.V.1, SC.VI.2	40 CFR 60.4205(a), Table 1 of 40 CFR Part 60, Subpart IIII
3. PM	0.20 g/kW-hr	Hourly	Each engine within FGEMERGENS	SC.V.1, SC.VI.2	40 CFR 60.4205(a), Table 1 of 40 CFR Part 60, Subpart IIII

g/kW-hr = grams per kilowatt-hour

**II. MATERIAL LIMIT(S)**

1. The permittee shall burn only diesel fuel in each engine within FGEMERGENS with a maximum sulfur content of 15 ppm (0.0015 percent) by weight and a minimum Cetane index of 40 or a maximum aromatic content of 35 volume percent. **(40 CFR 60.4207, 40 CFR 1090.305)**

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

1. The permittee shall not operate each engine within FGEMERGENS for more than 500 hours per year based on a 12-month rolling time period as determined at the end of each calendar month. The 500 hours includes the hours for the purpose of necessary maintenance checks and readiness testing as described in SC III.2. **(R 336.1225, R 336.1702(a), 40 CFR 52.21(c) & (d))**
2. The permittee may operate each engine within FGEMERGENS for no more than 100 hours per calendar year for the purpose of necessary maintenance checks and readiness testing, provided that the tests are recommended by Federal, State, or local government, the manufacturer, the vendor, the regional transmission organization or equivalent balancing authority and transmission operator, or the insurance company associated with the engine. The permittee may petition the Department for approval of additional hours to be used for maintenance checks and readiness testing. A petition is not required if the owner or operator maintains records indicating that Federal, State, or local standards require maintenance and testing of emergency internal combustion engines beyond 100 hours per calendar year. **(40 CFR 60.4211(f)(2))**

3. The permittee may operate each engine within FGEMERGENS up to 50 hours per calendar year in non-emergency situations, but those 50 hours are counted towards the 100 hours per calendar year provided for maintenance and testing as provided in 40 CFR 60.4211(f)(2). Except as provided in 40 CFR 60.4211(f)(3)(i), the 50 hours per calendar year for non-emergency situations cannot be used for peak shaving or non-emergency demand response, or to generate income for the permittee to supply non-emergency power as part of a financial arrangement with another entity. **(40 CFR 60.4211(f)(3))**
4. If the permittee purchased a certified engine, according to procedures specified in 40 CFR Part 60, Subpart IIII, for the same model year, the permittee shall meet the following requirements for each engine within FGEMERGENS:
  - a) Operate and maintain the certified engine and control device according to the manufacturer's emission-related written instructions,
  - b) Change only those emission-related settings that are permitted by the manufacturer, and
  - c) Meet the requirements as specified in 40 CFR 89, 94 and/or 1068, as they apply to the engine.If you do not operate and maintain the certified engine and control device according to the manufacturer's emission-related written instructions, the engine will be considered a non-certified engine. **(40 CFR 60.4211(a) & (c))**
5. If the permittee purchased a non-certified engine or a certified engine operating in a non-certified manner, the permittee shall keep a maintenance plan for each engine within FGEMERGENS and shall, to the extent practicable, maintain and operate the engine in a manner consistent with good air pollution control practice for minimizing emissions. **(40 CFR 60.4211(g)(3))**

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

1. The permittee shall equip and maintain each engine within FGEMERGENS with non-resettable hour meter to track the operating hours. **(R 336.1225, 40 CFR 60.4209)**
2. The maximum rated power output of EULABDIESELGEN shall not exceed 755 HP (500 kW), as certified by the equipment manufacturer. **(R 336.1225, R 336.1702(a), 40 CFR 60.4202, 40 CFR 60.4205, 40 CFR 89.112(a))**
3. The maximum rated power output of EUDIESELGEN shall not exceed 1744 HP (1300 kW), as certified by the equipment manufacturer. **(R 336.1225, R 336.1702(a), 40 CFR 60.4202, 40 CFR 60.4205, 40 CFR 89.112(a))**

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

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

1. If the either engine within FGEMERGENS is not installed, configured, operated, and maintained according to the manufacturer's emission-related written instructions, or the permittee changes emission-related settings in a way that is not permitted by the manufacturer, the permittee must demonstrate compliance as follows:
  - a) Conduct an initial performance test to demonstrate compliance with the applicable emission standards within 1 year after an engine and control device is no longer installed, configured, operated, and maintained in accordance with the manufacturer's emission-related written instructions, or within 1 year after you change emission-related settings in a way that is not permitted by the manufacturer.
  - b) If a performance test is required, the performance tests shall be conducted according to 40 CFR 60.4212.
  - c) Conduct subsequent performance testing every 8,760 hours of engine operation or every 3 years thereafter, whichever comes first, to demonstrate compliance with the applicable emission standards.

No less than 30 days prior to testing, a complete test plan shall be submitted to the AQD. The permittee must 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. **(40 CFR 60.4211(g)(3), 40 CFR 60.4212)**

## **VI. MONITORING/RECORDKEEPING**

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

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. **(R 336.1225, 40 CFR 52.21(c) & (d), 40 CFR Part 60, Subpart III)**
2. The permittee shall keep, in a satisfactory manner, the following records for each engine within FGEMERGENS:
  - a) For each certified engine: The permittee shall keep records of the manufacturer certification documentation.
  - b) For each uncertified engine: The permittee shall keep records of testing required in SC V.1.

The permittee shall keep all records on file and make them available to the Department upon request. **(40 CFR 60.4211)**

3. The permittee shall keep, in a satisfactory manner, the following records of maintenance activity for Each engine within FGEMERGENS:
  - a) For each certified engine: The permittee shall keep records of the manufacturer's emission-related written instructions, and records demonstrating that the engine has been maintained according to those instructions, as specified in SC III.4.
  - b) For each uncertified engine: The permittee shall keep records of a maintenance plan, as required by SC III.5, and maintenance activities.

The permittee shall keep all records on file and make them available to the Department upon request. **(40 CFR 60.4211)**

4. The permittee shall monitor and record, the total hours of operation for each engine within FGEMERGENS on a monthly and 12-month rolling time period basis, and the hours of operation during emergency and non-emergency service that are recorded through the non-resettable hour meter for each engine within FGEMERGENS, on a calendar year basis, in a manner acceptable to the AQD District Supervisor. The permittee shall document how many hours are spent for emergency operation of each engine within FGEMERGENS, including what classified the operation as emergency and how many hours are spent for non-emergency operation. **(40 CFR 60.4211, 40 CFR 60.4214)**
5. The permittee shall keep, in a satisfactory manner, fuel supplier certification records or fuel sample test data, for each delivery of diesel fuel oil used in each engine within FGEMERGENS, demonstrating that the fuel meets the requirement of 40 CFR 1090.305. The certification or test data shall include the name of the oil supplier or laboratory, the sulfur content, and cetane index or aromatic content of the fuel oil. **(40 CFR 60.4207(b), 40 CFR 1090.305)**

## **VII. REPORTING**

1. The permittee shall submit a notification specifying whether each engine within FGEMERGENS will be operated in a certified or a non-certified manner to the AQD District Supervisor, in writing, within 30 days following the initial startup of the engine and within 30 days of switching the manner of operation. **(40 CFR Part 60, Subpart III)**

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

NA

**IX. OTHER REQUIREMENT(S)**

1. The permittee shall comply with the provisions of the federal Standards of Performance for New Stationary Sources as specified in 40 CFR Part 60, Subparts A and IIII, as they apply to each engine within FGEMERGENS. **(40 CFR Part 60, Subparts A & IIII, 40 CFR 63.6590(c))**
2. The permittee shall comply with the provisions of the National Emission Standards for Hazardous Air Pollutants as specified in 40 CFR Part 63, Subparts A and ZZZZ, as they apply to each engine within FGEMERGENS. **(40 CFR Part 63, Subparts A & ZZZZ, 40 CFR 63.6585)**

**FG-IPA-USE  
FLEXIBLE GROUP CONDITIONS**

**DESCRIPTION**

Flexible group which includes all IPA use throughout the facility for cleaning and disinfecting process equipment and removing labels from containers. Most IPA usage is in Building 100 and 43

**Emission Unit:** EU-103-PACKAGE, EU-104-PREP, EU-114-WIPEUP

**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. Isopropyl alcohol (IPA)	24 tpy	12-month rolling time period, as determined at the end of each calendar month.	FG-IPA-USE	SC VI.2	R 336.1225, R 336.1702(a)

**II. MATERIAL LIMIT(S)**

NA

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

NA

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

NA

**V. TESTING/SAMPLING**

NA

**VI. MONITORING/RECORDKEEPING**

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

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. **(R 336.1225, R 336.1702(a))**
2. The permittee shall keep the following information on a calendar basis for FG-IPA-USE:
  - a) Gallons and pounds of IPA used per month.
  - b) IPA emission calculations determining the monthly emission rate in tons per calendar month, and the annual emission rate in tons per 12-month rolling time period as determined at the end of each calendar month.

The permittee shall keep the records on file at the facility, in a format acceptable to the AQD District Supervisor, and make them available to the Department upon request. **(R 336.1225, R 336.1702(a))**

**VII. REPORTING**

NA

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

NA

**IX. OTHER REQUIREMENT(S)**

NA

## FGFACILITY CONDITIONS

### DESCRIPTION

The following conditions apply source-wide to all process equipment including equipment covered by other permits, grand-fathered equipment, and exempt equipment.

### 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. Individual HAP	8.9 tpy	12-month rolling time period, as determined at the end of each calendar month.	FGFACILITY	SC.VI 2	R 336.1205(1)(a) & (3)
2. Total HAPs	22.4 tpy	12-month rolling time period, as determined at the end of each calendar month.	FGFACILITY	SC.VI 2	R 336.1205(1)(a) & (3)

#### II. MATERIAL LIMIT(S)

NA

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

NA

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

NA

#### V. TESTING/SAMPLING

NA

#### VI. MONITORING/RECORDKEEPING

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

1. The permittee shall complete all required calculations 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 recordkeeping, reporting or notification special condition. **(R 336.1205(1)(a) & (3))**
2. The permittee shall keep, in a satisfactory manner, individual and aggregate HAP emission calculations determining the annual emission rate of each in tons per 12-month rolling time period as determined at the end of each calendar month, as required by SC I.1, I.2. The permittee shall keep all records on file at location approved by the AQD District Supervisor and make them available to the Department upon request. **(R 336.1205(1)(a) & (3))**

**VII. REPORTING**

NA

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

NA

**IX. OTHER REQUIREMENT(S)**

NA