

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

February 17, 2021

**PERMIT TO INSTALL
73-17C**

**ISSUED TO
Zoetis LLC**

**LOCATED AT
2605 East Kilgore Road
Kalamazoo, Michigan 49001**

**IN THE COUNTY OF
Kalamazoo**

**STATE REGISTRATION NUMBER
B7149**

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: January 25, 2021	
DATE PERMIT TO INSTALL APPROVED: February 17, 2021	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 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 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 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))**
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))	Flexible Group ID
EUPilotFBGD	Pilot scale batch fluidized bed granulator dryer (FBGD). Maximum batch size is 60 kilograms. Emissions are exhausted to DUST5120-1.	NA
EUB248WeighA	Building 248 Oral Solid Dosage (OSD) weighing area A. Emissions are exhausted to DUST4300-2 and also vented inside the building in downflow booth with HEPA control.	FGB248OSD
EUB248L1Blend	Building 248 OSD Line 1 blending, mechanical processing, and dispensing. Emissions are exhausted to DUST4300-2.	FGB248OSD
EUB248L1Tablet	Building 248 OSD Line 1 tablet compression. Emissions are exhausted to DUST4300-1.	FGB248OSD
EUB248L1TabCoat	Building 248 OSD Line 1 tablet coating (aqueous). Emissions are exhausted to DUST4340-1.	FGB248OSD
EUB248OSDPkg	Building 248 OSD packaging. Emissions are exhausted either to DCOSDPACK, which vents inside the building, or to DUST4003-1.	FGB248OSD
EUB248L2Blend	Building 248 OSD Line 2 blending, mechanical processing, and dispensing. Emissions are exhausted to DUST4003-1.	FGB248OSD
EUB248L2HSG	Building 248 OSD Line 2 high shear granulation. Emissions are exhausted to DUST4003-1 and L2HSGHEPA.	FGB248OSD
EUB248L2FBGDAq	Building 248 OSD Line 2 aqueous fluidized bed granulator dryer. Emissions are exhausted to L2FBGDAqHEPA.	FGB248OSD
EUB248L3Blend	Building 248 OSD Line 3 blending, mechanical processing, and dispensing. Emissions are exhausted to DUST4001-1.	FGB248OSD
EUB248L3HSG	Building 248 OSD Line 3 high shear granulation. Emissions are exhausted to DUST4001-1 and L3HSGHEPA.	FGB248OSD
EUB248L3FBGDAq	Building 248 OSD Line 3 aqueous fluidized bed granulator dryer. Emissions are exhausted to L3FBGDAqHEPA.	FGB248OSD
EUB248L3FBGDSol	Building 248 OSD Line 3 solvent fluidized bed granulator dryer. Emissions are exhausted to L3FBGDSolHEPA and the thermal oxidizer.	FGB248OSD
EUB248WeighB	Building 248 OSD weighing area B. Emissions are exhausted to DUST4001-1 and also vented inside the building in downflow booth with HEPA control.	FGB248OSD
EUB248L2&3TabA	Building 248 OSD Lines 2 and 3 tablet compression unit A. Emissions are exhausted to DUST4002-1.	FGB248OSD
EUB248L2&3TabB	Building 248 OSD Lines 2 and 3 tablet compression unit B. Emissions are exhausted to DUST4002-1.	FGB248OSD
EUB248L2&3TabC	Building 248 OSD Lines 2 and 3 tablet compression unit C. Emissions are exhausted to DUST4002-1.	FGB248OSD

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.

**EUPilotFBGD
EMISSION UNIT CONDITIONS**

DESCRIPTION

Pilot scale batch fluidized bed granulator dryer. Maximum batch size is 60 kilograms. Emissions are exhausted to DUST5120-1.

Flexible Group ID: NA

POLLUTION CONTROL EQUIPMENT

One dust collector followed by a HEPA filter: DUST5120-1

I. EMISSION LIMIT(S)

Pollutant	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. VOC and acetone	3.8 tpy	12-month rolling time period as determined at the end of each calendar month	EUPilotFBGD	SC VI.2, VI.3	R 336.1224, R 336.1702(a)
2. PM	0.003 lb/hr	Hourly	EUPilotFBGD	SC VI.5	R 336.1224, R 336.1225, R 336.1331

II. MATERIAL LIMIT(S)

Material	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. Solid raw material processed	4,100 lbs per month	Calendar month	EUPilotFBGD	SC VI.4	R 336.1225, 40 CFR 52.21(c)&(d)
2. Total organic solvent use ^A	7,600 lbs per year	12-month rolling time period as determined at the end of each calendar month	EUPilotFBGD	SC VI.2	R 336.1224, R 336.1702(a)
3. Organic solvent use	30 kg per batch ¹	Each solvent-based batch	EUPilotFBGD	SC VI.6	R 336.1225

^A "Organic solvent use" includes organic chemical use as a solvent in EUPilotFBGD batches and organic solvent use for cleanup of equipment in EUPilotFBGD.

III. PROCESS/OPERATIONAL RESTRICTION(S)

NA

IV. DESIGN/EQUIPMENT PARAMETER(S)

1. The permittee shall not operate EUPilotFBGD unless the FBGD dust collector with HEPA filter is installed, maintained, and operated in a satisfactory manner. (R 336.1224, R 336.1225, R 336.1331, R 336.1910, 40 CFR 52.21(c)&(d))

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 complete all required calculations and records 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), 40 CFR 52.21(c)&(d))**
2. The permittee shall keep a record of the organic solvents used in EUPilotFBGD during each calendar month and during the 12-month rolling time period ending that 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 336.1224, R 336.1702(a))**
3. The permittee shall calculate the VOC and acetone emission rate from EUPilotFBGD 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 336.1224, R 336.1702(a))**
4. The permittee shall keep a record of the amount of solid raw material processed in EUPilotFBGD during 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, 40 CFR 52.21(c)&(d))**
5. The permittee shall conduct a monthly visible emissions check of the FBGD dust collector during routine operating conditions. For this condition, such checks do not have to be in accordance with Method 9. If a check reveals any visible emissions, the permittee shall inspect the particulate filter and perform any maintenance required to eliminate visible emissions. **(R 336.1910)**
6. The permittee shall keep a record of the amount of organic solvent used in each organic solvent-based batch processed in EUPilotFBGD. 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.¹ **(R 336.1225)**
7. Before using in EUPilotFBGD any material for which the permittee requests an AQD toxics determination for EUPilotFBGD pursuant to SC VII.1, the permittee shall follow the procedure below.¹ **(R 336.1225)**
 - a) The permittee shall determine whether the material is a TAC, based on the definition of toxic air contaminant in Rule 120 (R 336.1120).
 - b) If the material is a TAC, the permittee shall determine whether the material is a carcinogen as defined in Rule 103 or is listed in Table 20 of Rule 226.
 - c) The permittee shall record all the following:
 - i. The material's name and either its Chemical Abstract Service Registry Number (CAS Number) or another identifier specific to the substance. If no CAS Number or other publicly available identifier is available, the chemical structure or partial chemical structure must be recorded in enough detail to adequately describe the compound.
 - ii. If applicable, the basis for determining the material is not a TAC, including resources used to make this determination.
 - iii. If applicable, the basis for determining the material is not a carcinogen as defined in Rule 103 and is not listed in Table 20 of Rule 226.
 - iv. The maximum one-hour and monthly emission rates for the material, with supporting calculations.
 - v. The active permit number.
 - vi. The date when the permittee proposes to begin using the material in EUPilotFBGD.

- d) The permittee shall not use the material in EUPilotFBGD until after one of the following has occurred following submittal of the report specified in SC VII.1:
 - i. The permittee has received AQD communication that the material is not a TAC.
 - ii. The permittee has received AQD communication that the material is not a carcinogen as defined in Rule 103 and is not listed in Table 20 of Rule 226.
 - iii. Thirty days have passed since submitting the report specified in SC VII.1.
- 8. The permittee shall keep a record of all materials processed in EUPilotFBGD during each calendar month. Records shall also be maintained to include the information listed in a), b), and c) below for each material meeting one of the following criteria. 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 material is listed in the Table of Materials in Appendix A.
 - The permittee has requested an AQD toxics determination for EUPilotFBGD for the material.
 - a) Name
 - b) CAS Number or another identifier specific to the substance. If no CAS Number or other publicly available identifier is available, the chemical structure or partial chemical structure must be recorded in enough detail to adequately describe the compound.
 - c) All the following that apply to the material:
 - i. Whether the material is listed in the Table of Materials in Appendix A
 - ii. The date the permittee submitted a request for an AQD toxics determination for EUPilotFBGD for the material.
 - iii. The basis for determining the material is not a TAC.

VII. REPORTING

- 1. This condition applies to any material for which the permittee requests an AQD toxics determination for EUPilotFBGD. No less than 30 days before first using the material in EUPilotFBGD, the permittee shall submit all records required by SC VI.3.d to the AQD District Supervisor in an acceptable format. The AQD will do one of the following within 30 days of receipt of the submittal:¹ **(R 336.1225, R 336.1226(a))**
 - a) Communicate that the material is not a TAC.
 - b) Communicate that the material is not a carcinogen and is not listed in Table 20.
 - c) Communicate that the material is a carcinogen or is listed in Table 20.

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. SV-DUST5120-1 (Fluid Bed Granulator Dryer [Pilot Plant])	14	32	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).

FLEXIBLE GROUP SPECIAL CONDITIONS

FLEXIBLE GROUP SUMMARY TABLE

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

Flexible Group ID	Flexible Group Description	Associated Emission Unit IDs
FGB248OSD	The Lines 1, 2, and 3 OSD manufacturing equipment in Building 248, including the Line 2 and Line 3 fluidized bed granulator dryers.	EUB248WeighA, EUB248WeighB, EUB248L1Blend, EUB248L2Blend, EUB248L3Blend, EUB248L2HSG, EUB248L3HSG, EUB248L2FBGDAq, EUB248L3FBGDAq, EUB248L3FBGDSol, EUB248L1Tablet, EUB248L1TabCoat, EUB248L2&3TabA, EUB248L2&3TabB, EUB248L2&3TabC, EUB248OSDPkg

**FGB248OSD
FLEXIBLE GROUP CONDITIONS**

DESCRIPTION

The Lines 1, 2, and 3 OSD manufacturing equipment in Building 248, including the Line 2 and Line 3 fluidized bed granulator dryers.

Emission Unit: EUB248WeighA, EUB248WeighB, EUB248L1Blend, EUB248L2Blend, EUB248L3Blend, EUB248L2HSG, EUB248L3HSG, EUB248L2FBGDAq, EUB248L3FBGDAq, EUB248L3FBGDSol, EUB248L1Tablet, EUB248L1TabCoat, EUB248L2&3TabA, EUB248L2&3TabB, EUB248L2&3TabC, EUB248OSDPkg

POLLUTION CONTROL EQUIPMENT

Twelve PM control devices:

- DUST4300-2 (dust collector followed by HEPA filter)
- DUST4300-1 (dust collector followed by HEPA filter)
- DUST4340-1 (dust collector followed by HEPA filter)
- DCOSDPACK (dust collector followed by HEPA filter, vents inside the building)
- DUST4003-1 (dust collector followed by HEPA filter)
- DUST4001-1 (dust collector followed by HEPA filter)
- L2FBGDAqHEPA (HEPA filter only)
- L3FBGDAqHEPA (HEPA filter only)
- L3FBGDSolHEPA (HEPA filter only)
- L2HSGHEPA (HEPA filter only)
- L3HSGHEPA (HEPA filter only)
- DUST4002-1 (dust collector followed by HEPA filter)

Thermal oxidizer following L3FBGDSolHEPA

I. EMISSION LIMIT(S)

Pollutant	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. VOC	5.1 tpy	12-month rolling time period as determined at the end of each calendar month	FGB248OSD	SC VI.2, VI.3	R 336.1702(a)
2. VOC	6.0 lb/hr	Hourly	EUB248L3FBGDSol	SC VI.4	R 336.1702(a)
3. Each Category 226(a) TAC ^A	Less than 10 lbs/month ¹	Calendar month	FGB248OSD	SC VI.8	R 336.1225, R 336.1226(a)
4. Each Category 226(a) TAC	Less than 0.14 lb/hr ¹	Hourly	FGB248OSD	SC IV.1, VI.6	R 336.1225, R 336.1226(a)

^A A "Category 226(a) TAC" is a TAC that meets all the criteria listed below, except that any TAC with "Y" in the "Rule 225" column or designated with a "D" footnote in the table in Appendix B is not a Category 226(a) TAC.

- It is not a carcinogen
- It is not listed in Table 20 of Rule 226 (R 336.1226)
- It has emissions < 0.14 lb/hr and < 10 lb/month

II. MATERIAL LIMIT(S)

Material	Limit	Time Period / Operating Scenario	Equipment	Monitoring / Testing Method	Underlying Applicable Requirements
1. Total material processed ^A	157,200 lbs per month ¹	Calendar month	FGB248OSD batches	SC VI.6	R 336.1225, R 336.1226(a)
2. Each API material ^B processed	39,300 lbs per month ¹	Calendar month	FGB248OSD batches	SC VI.6	R 336.1225, R 336.1226(a)
3. Total organic cleaning solvent use	6,400 lbs per year	12-month rolling time period as determined at the end of each calendar month	FGB248OSD	SC VI.2	R 336.1702(a)

^A "Total material processed" does not include coating materials.

^B "API material" refers to materials that are active pharmaceutical ingredients.

III. PROCESS/OPERATIONAL RESTRICTION(S)

1. The permittee shall maintain a minimum overall VOC control efficiency of 95 percent across the EUB248L3FBGDSol thermal oxidizer. **(R 336.1702(a), R 336.1910)**
2. The permittee shall not install the EUB248L3FBGDSol thermal oxidizer until an approvable design analysis demonstrating the thermal oxidizer will attain at least 95 percent VOC control efficiency, with supporting final plans and specifications, has been submitted to the AQD District Supervisor. **(R 336.1702(a))**

IV. DESIGN/EQUIPMENT PARAMETER(S)

1. The permittee shall not operate process equipment in FGB248OSD unless the associated PM control device is installed, maintained, and operated in a satisfactory manner. **(R 336.1224, R 336.1225, R 336.1331, R 336.1910)**
2. The permittee shall equip and maintain the EUB248L3FBGDSol thermal oxidizer with an instrument to indicate the combustion chamber temperature. **(R 336.1910)**
3. The permittee shall not operate EUB248L3FBGDSol unless the thermal oxidizer is installed, maintained, and operated in a satisfactory manner. Satisfactory operation of the thermal oxidizer includes maintaining a minimum temperature of 1400 degrees F in the combustion chamber, or an alternate temperature or averaging time approved by the AQD District Supervisor. **(R 336.1225, R 336.1702(a), R 336.1910)**

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 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 336.1226(a), R 336.1702(a))**
2. The permittee shall keep a record of the amount, in pounds, of organic cleaning solvents used in FGB248OSD during each calendar month and during the 12-month rolling time period ending that 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 336.1702(a))**

3. The permittee shall calculate the VOC emission rate from FGB248OSD monthly, for the calendar month and for the 12-month rolling time period ending that month, using emission factors and control efficiencies used in the review of PTI No. 73-17B, or an alternate 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 continuously monitor, in a satisfactory manner, the combustion chamber temperature in the EUB248L3FBGDSol thermal oxidizer while EUB248L3FBGDSol is operating. Once each shift EUB248L3FBGDSol operates, the permittee shall record, in a satisfactory manner, the combustion chamber temperature while EUB248L3FBGDSol is operating. The permittee shall keep all records on file at the facility and make them available to the Department upon request. **(R 336.1910)**
5. The permittee shall conduct a monthly visible emissions check of the emission control devices listed below during routine operating conditions. For this condition, such checks do not have to be in accordance with Method 9. If a check reveals any visible emissions, the permittee shall inspect the emission control device and perform any maintenance required to eliminate visible emissions. **(R 336.1910)**
 - a) DUST4300-2
 - b) DUST4300-1
 - c) DUST4340-1
 - d) DCOSDPACK
 - e) DUST4003-1
 - f) L2FBGDAqHEPA
 - g) L3FBGDAqHEPA
 - h) L3FBGDSolHEPA
 - i) L2HSGHEPA
 - j) L3HSGHEPA
 - k) DUST4002-1
 - l) DUST4001-1
6. The permittee shall keep, in a satisfactory manner, all monthly records listed below, as required by SC II.1 and II.2, on file at the facility and make them available to the Department upon request.¹ **(R 336.1225, R 336.1226(a))**
 - a. Total material processed in FGB248OSD batches, excluding coating material.
 - b. Each API material processed in FGB248OSD batches.
7. Before using in FGB248OSD any material for which the permittee requests an AQD toxics determination for FGB248OSD pursuant to SC VII.2, the permittee shall follow the procedure below.¹ **(R 336.1225)**
 - a) The permittee shall determine whether the material is a TAC, based on the definition of toxic air contaminant in Rule 120 (R 336.1120).
 - b) If the material is a TAC, the permittee shall determine whether the material is a carcinogen as defined in Rule 103 or is listed in Table 20 of Rule 226.
 - c) The permittee shall record all the following:
 - i. The material's name and either its Chemical Abstract Service Registry Number (CAS Number) or another identifier specific to the substance. If no CAS Number or other publicly available identifier is available, the chemical structure or partial chemical structure must be recorded in enough detail to adequately describe the compound.
 - ii. If applicable, the basis for determining the material is not a TAC, including resources used to make this determination.
 - iii. If applicable, the basis for determining the material is not a carcinogen as defined in Rule 103 and is not listed in Table 20 of Rule 226.
 - iv. The maximum one-hour and monthly emission rates for the material, with supporting calculations.
 - v. The active permit number.
 - vi. The date when the permittee proposes to begin using the material in FGB248OSD.
 - d) The permittee shall not use the material in FGB248OSD until after one of the following has occurred following submittal of the report specified in SC VII.2:
 - i. The permittee has received AQD communication that the material is not a TAC.
 - ii. The permittee has received AQD communication that the material is not a carcinogen as defined in Rule 103 and is not listed in Table 20 of Rule 226.

- iii. Thirty days have passed since submitting the report specified in SC VII.2.
8. The permittee shall keep a record of all materials processed in FGB248OSD during each calendar month. Records shall also be maintained to include the information listed in a), b), and c) below for each material meeting one of the following criteria. 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 material is listed in the Table of Materials in Appendix B.
 - The permittee has requested an AQD toxics determination for FGB248OSD for the material.
- a) Name
 - b) CAS Number or another identifier specific to the substance. If no CAS Number or other publicly available identifier is available, the chemical structure or partial chemical structure must be recorded in enough detail to adequately describe the compound.
 - c) All the following that apply to the material:
 - i. Whether the material is listed in the Table of Materials in Appendix B
 - ii. The date the permittee submitted a request for an AQD toxics determination for FGB248OSD for the material.
 - iii. The basis for determining the material is not a TAC
9. The permittee shall keep the design analysis and supporting final plans and specifications for the EUB248L3FBGDSol thermal oxidizer required by SC III.2 on file at the facility for the life of the thermal oxidizer and make them available to the Department upon request. **(R 336.1702(a))**

VII. REPORTING

- 1. Within 30 days after completion of the installation, construction, reconstruction, relocation, or modification authorized by this Permit to Install, the permittee or the authorized agent pursuant to Rule 204, shall notify the AQD District Supervisor, in writing, of the completion of the activity. Completion of the installation, construction, reconstruction, relocation, or modification is considered to occur not later than commencement of trial operation of EUB248L3FBGDSol. **(R 336.1201(7)(a))**
- 2. This condition applies to any material for which the permittee requests an AQD toxics determination for FGB248OSD. No less than 30 days before first using the material in FGB248OSD, the permittee shall submit all records required by SC VI.3.d to the AQD District Supervisor in an acceptable format. The AQD will do one of the following within 30 days of receipt of the submittal:¹ **(R 336.1225, R 336.1226(a))**
 - a) Communicate that the material is not a TAC.
 - b) Communicate that the material is not a carcinogen and is not listed in Table 20.
 - c) Communicate that the material is a carcinogen or is listed in Table 20.

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. SV-DUST4340-1 (OSD Line 1 Coating Dust Collector)	26	28	R 336.1225, 40 CFR 52.21(c) & (d)
2. SV-DUST4300-2 (OSD Line 1 Blending & Weigh A Dust Collector)	16	28	R 336.1225, 40 CFR 52.21(c) & (d)
3. SV-DUST4300-1 (OSD Line 1 Tableting Dust Collector)	14	28	R 336.1225, 40 CFR 52.21(c) & (d)

Stack & Vent ID	Maximum Exhaust Diameter / Dimensions (inches)	Minimum Height Above Ground (feet)	Underlying Applicable Requirements
4. SV-DUST4003-1 (OSD Line 2 Blending Dust Collector)	20	60	R 336.1225, 40 CFR 52.21(c)&(d)
5. SV-DUST4001-1 (OSD Line 3 & Weigh B Dust Collector)	20	60	R 336.1225, 40 CFR 52.21(c)&(d)
6. SV-DUST4002-1 (OSD Lines 2 and 3 Tableting Dust Collector)	20	60	R 336.1225, 40 CFR 52.21(c)&(d)
7. SV-L2FBGDAq (OSD Line 2 aqueous FBGD)	24	60	R 336.1225, 40 CFR 52.21(c)&(d)
8. SV-L3FBGDAq (OSD Line 3 aqueous FBGD)	20	60	R 336.1225, 40 CFR 52.21(c)&(d)
9. SV-L3FBGDSol (OSD Line 3 solvent FBGD)	18 x 18 ^A	25	R 336.1225, 40 CFR 52.21(c)&(d)
^A Or other dimensions with a maximum interior horizontal cross-section area of 324 square inches.			

IX. OTHER REQUIREMENT(S)

NA

Footnotes:

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

APPENDIX A: Materials Identified as Emitted from EUPilotFBGD

The following table lists materials identified as emitted from EUPilotFBGD, along with related AQD determinations made at the time each material was reviewed. The table is current as of the date PTI No. 73-17B was issued and does not list materials submitted to the AQD after that date through the process identified in the Special Conditions for EUPilotFBGD.

Material	CAS Number	TAC ^A	Rule 226(a)(ii) ^B	Rule 225 ^C
Magnesium stearate	557-04-0	Y	Y	Y
2,6-Di-tert-butyl-p-cresol	128-37-0	Y	N	Y
Colloidal silicon dioxide	112926-00-8 112945-52-5 7631-86-9	Y	Y	Y
Fumed silica	60676-86-0	Y	Y	Y
Talc	14807-96-6	Y	N	Y
Carboxymethylcellulose sodium	9004-32-4	Y	Y	Y
Diethyl phthalate	84-66-2	Y	Y	Y
Glycerin/glycerol	56-81-5	Y	Y	Y
Poloxamer	9003-11-6	Y	Y	Y
Polyethylene glycol	25322-68-3	Y	Y	Y
Povidone	9003-39-8	Y	Y	Y
Titanium dioxide	13463-67-7	Y	Y	Y
Triacetin	102-76-1	Y	Y	Y
Triethyl citrate	77-93-0	Y	Y	Y
Sulfuric acid	7664-93-9	Y		Y
Isopropyl alcohol	67-63-0	Y	Y	Y
Ethyl alcohol	64-17-5	Y	Y	Y
Amorphous Silica	112926-00-8	Y	Y	Y
Acetone	67-64-1	Y	Y	Y
Carprofen	53716-49-7	Y	Y	
Ivermectin	70288-86-7	Y	Y	
Lasalocid sodium	25999-20-6	Y	Y	
Milbemycin oxime	129496-10-2	Y	Y	
Monensin Sodium	22373-78-0	Y	Y	
Nicarbazin	330-95-0	Y	Y	
Praziquantel	55268-74-1	Y	Y	
Selamectin	220119-17-5	Y	Y	
Tiamulin hydrogen fumarate	55297-96-6	Y	Y	
Toceranib phosphate	874819-74-6	Y	Y	
Oclacitinib maleate	1208319-27-0	Y	Y	
Mavacoxib	170569-88-7	Y	Y	
Moxidectin	113507-06-5	Y	Y	
Pyrantel pamoate	22204-24-6	Y	Y	
Sarolaner	1398609-39-6	Y	Y	
Toceranib	356068-94-5	Y	Y	
Calcium stearate	1592-23-0	Y	Y	
Decanedioic acid	109-43-3	Y	Y	
Methacrylic acid-ethyl acrylate copolymer	25212-88-8	Y	Y	
Propylene glycol	57-55-6	Y	Y	
Sodium lauryl sulfate	151-21-3	Y	Y	
Cellulose Acetate Phthalate	9004-38-0	Y	Y	
Polymethacrylates	9010-88-2	Y	Y	
Polymethacrylates	24938-16-7	Y	Y	
Polymethacrylates	25086-15-1	Y	Y	
Polymethacrylates	33434-24-1	Y	Y	

Material	CAS Number	TAC ^A	Rule 226(a)(ii) ^B	Rule 225 ^C
Cyclodextrin	7585-39-9	Y	Y	
FD&C Blue #2	860-22-0 16521-38-3	Y	Y	
Ponceau 4R	2611-82-7	Y	Y	
FD&C Yellow #6	2783-94-0 15790-07-5	Y	Y	
Carboxymethylcellulose calcium	9050-04-8	Y	Y	
Butylated hydroxyanisole	25013-16-5	Y ^D		
Calcium phosphate dibasic, anhydrous	7757-93-9	Y ^D		
Hydroxy Propyl Methyl Cellulose	9004-65-3	Y ^D		
Sodium Chloride	7647-14-5	Y ^D		
Polysorbate 80	9005-65-6	Y ^D		
Polyvinyl alcohol (polymer)	9002-89-5	Y ^D		
Monosodium phosphate	7558-80-7	Y ^D		
Polydextrose	68424-04-4	Y ^D		
Hydroxy Propyl Cellulose	9004-64-2	Y ^D		
Croscarmellose Sodium	74811-65-7	Y ^D		
Disodium EDTA	6381-92-6	Y	Y	
Meglumine	6284-40-8	Y	Y	
FD&C Blue #1	3844-45-9	Y	Y	
FD&C Red #40	25956-17-6 68583-95-9	Y	Y	
Microcrystalline Cellulose	9004-34-6	N		
Lactose Monohydrate	5989-81-1 64044-51-5 63-42-3	N		
Palatable Base Granules (consisting of sugar; maize starch; and calcium phosphate dibasic, anhydrous)		N		
Sugar	57-50-1	N		
Maize starch	9005-25-8	N		
Water	7732-18-5	N		
Red Iron Oxide Non-Irradiated	1309-37-1	N		
Lecithin		N		
Sodium Starch Glycolate	9063-38-1	N		
Medium Chain Triglycerides		N		
Glycerol Mono-Stearate	31566-31-1	N		
Xanthan Gum	11138-66-2	N		
AFB Palatant (includes 10% sodium sulfate)		N		
Sodium Sulfate	7757-82-6	N		
Brewer Yeast	84604-16-0	N		
Egg Flavor		N		
Chicken Flavor		N		
Soybean Oil	8001-22-7	N		
Corn Starch		N		
Liver Powder		N		
Wheat Germ		N		
Sugar	57-50-1	N		
Dextrate	50-99-7	N		
Dextrate	39404-33-6	N		
Dextrate	68131-37-3	N		
Hydroxypropyl Methylcellulose Phthalate	9050-31-1	N		
Gelatin	9000-70-8	N		
Hydrolyzed Vegetable Protein		N		

Material	CAS Number	TAC ^A	Rule 226(a)(ii) ^B	Rule 225 ^C
Calcium Carbonate		N		
Calcium Phosphate Tribasic	7758-87-4	N		
Calcium Sulfate		N		
Cellulose Acetate	9004-35-7	N		
Cellulose, Powdered		N		
Citric Acid Monohydrate	5949-29-1	N		
Dextrose (Corn Sugar & Starch Sugar)		N		
Ethylcellulose	9004-57-3	N		
Fructose		N		
Glucose Liquid	8027-56-3	N		
Hydroxyethyl cellulose	9004-62-0	N		
Maltodextrin	9050-36-6	N		
Mannitol	69-65-8	N		
Starch - Pregelatinized	9005-25-8	N		
Starch - Sterilizable		N		
Sucrose	57-50-1	N		
Compressible Sugar	64294-03-7	N		
Compressible Sugar	66748-03-6	N		
Confectioner's Sugar	57-50-1, 9005-25-8	N		
Sugar Spheres		N		
Microcrystalline Wax	63231-60-7	N		
Corn syrup		N		

- ^A Indicates an AQD determination on whether the material is a toxic air contaminant (TAC):
- “Y” indicates the material is a TAC.
 - “N” indicates the material is not a TAC.
- ^B Indicates an AQD determination on whether the material meets the criteria of Rule 226(a)(ii):
- “Y” indicates the material is not a carcinogen and is not listed in Table 20.
 - “N” indicates the material is a carcinogen or is listed in Table 20, or both.
 - If there is no entry in this column for a material, the AQD made no determination.
- ^C Indicates an AQD determination on whether the emission rate for the material the applicant provided to the AQD met the requirement of Rule 225(1).
- “Y” indicates the AQD made this determination for the material.
 - If there is no entry in this column for a material, the AQD made no determination.
- ^D Applies to an AQD determination that a material is a TAC, as in note A above. The AQD has not established a screening level for any TAC with this note, but has determined that in lieu of setting a screening level, the primary NAAQS for particulate matter (PM2.5, PM10) are reasonable and appropriate health protective levels for the particulate. The AQD considered the combined ambient impact of all particulate TAC emissions from the process in the review of PTI No. 73-17A.

APPENDIX B: Materials Identified as Emitted from FGB248OSD

The following table lists materials identified as emitted from FGB248OSD, along with related AQD determinations made at the time each material was reviewed. The table is current as of the date PTI No. 73-17B was issued and does not list materials submitted to the AQD after that date through the process identified in the Special Conditions for FGB248OSD.

Material	CAS Number	TAC^A	Rule 226(a)(ii)^B	Rule 225^C
Magnesium stearate	557-04-0	Y	Y	Y
Butylated hydroxytoluene	128-37-0	Y	N	Y
Colloidal silicon dioxide	112926-00-8, 112945-52-5	Y	Y	Y
Colloidal silicon dioxide	7631-86-9	Y	Y	Y
Fumed silica	60676-86-0	Y	Y	Y
Talc	14807-96-6	Y	N	Y
Carboxymethylcellulose sodium	9004-32-4	Y	Y	Y
Diethyl phthalate	84-66-2	Y	Y	Y
Glycerin/glycerol	56-81-5	Y	Y	Y
Poloxamer	9003-11-6	Y	Y	Y
Polyethylene glycol	25322-68-3	Y	Y	Y
Povidone	9003-39-8	Y	Y	Y
Titanium dioxide	13463-67-7	Y	Y	Y
Triacetin	102-76-1	Y	Y	Y
Triethyl citrate	77-93-0	Y	Y	Y
Sulfuric acid	7664-93-9	Y		Y
Isopropyl alcohol	67-63-0	Y	Y	Y
Ethyl alcohol	64-17-5	Y	Y	Y
Carprofen	53716-49-7	Y	Y	
Ivermectin	70288-86-7	Y	Y	
Lasalocid sodium	25999-20-6	Y	Y	
Milbemycin oxime	129496-10-2	Y	Y	
Monensin Sodium	22373-78-0	Y	Y	
Nicarbazin	330-95-0	Y	Y	
Praziquantel	55268-74-1	Y	Y	
Selamectin	220119-17-5	Y	Y	
Tiamulin hydrogen fumarate	55297-96-6	Y	Y	
Toceranib phosphate	874819-74-6	Y	Y	
Oclacitinib maleate	1208319-27-0	Y	Y	
Mavacoxib	170569-88-7	Y	Y	
Moxidectin	113507-06-5	Y	Y	
Pyrantel pamoate	22204-24-6	Y	Y	
Sarolaner	1398609-39-6	Y	Y	
Toceranib	356068-94-5	Y	Y	
Calcium stearate	1592-23-0	Y	Y	
Decanedioic acid	109-43-3	Y	Y	
Methacrylic acid-ethyl acrylate copolymer	25212-88-8	Y	Y	
Propylene glycol	57-55-6	Y	Y	
Sodium lauryl sulfate	151-21-3	Y	Y	
Cellulose Acetate Phthalate	9004-38-0	Y	Y	
Polymethacrylates	9010-88-2	Y	Y	
Polymethacrylates	24938-16-7	Y	Y	
Polymethacrylates	25086-15-1	Y	Y	
Polymethacrylates	33434-24-1	Y	Y	
Cyclodextrin	7585-39-9	Y	Y	
FD&C Blue #2	860-22-0	Y	Y	

Material	CAS Number	TAC ^A	Rule 226(a)(ii) ^B	Rule 225 ^C
FD&C Blue #2	16521-38-3	Y	Y	
Ponceau 4R	2611-82-7	Y	Y	
FD&C Yellow #6	2783-94-0	Y	Y	
FD&C Yellow #6	15790-07-5	Y ^D		
Carboxymethylcellulose calcium	9050-04-8	Y	Y	
Butylated hydroxyanisole	25013-16-5	Y ^D		
Calcium phosphate dibasic, anhydrous	7757-93-9	Y ^D		
Hydroxy Propyl Methyl Cellulose	9004-65-3	Y ^D		
Sodium Chloride	7647-14-5	Y ^D		
Polysorbate 80	9005-65-6	Y ^D		
Polyvinyl alcohol (polymer)	9002-89-5	Y ^D		
Monosodium phosphate	7558-80-7	Y ^D		
Polydextrose	68424-04-4	Y ^D		
Hydroxy Propyl Cellulose	9004-64-2	Y ^D		
Croscarmellose Sodium	74811-65-7	Y ^D		
Disodium EDTA	6381-92-6	Y ^D		
Meglumine	6284-40-8	Y ^D		
FD&C Blue #1	3844-45-9	Y ^D		
FD&C Red #40	25956-17-6	Y ^D		
FD&C Red #40	68583-95-9	Y ^D		
Microcrystalline Cellulose	9004-34-6	N		
Lactose Monohydrate	5989-81-1, 64044-51-5, 63-42-3	N		
Palatable Base Granules (consisting of sugar; maize starch; and calcium phosphate dibasic, anhydrous)		N		
Sugar	57-50-1	N		
Maize starch	9005-25-8	N		
Water	7732-18-5	N		
Red Iron Oxide Non-Irradiated	1309-37-1	N		
Lecithin		N		
Sodium Starch Glycolate	9063-38-1	N		
Medium Chain Triglycerides		N		
Glycerol Mono-Stearate	31566-31-1	N		
Xanthan Gum	11138-66-2	N		
AFB Palatant (includes 10% sodium sulfate)		N		
Sodium Sulfate	7757-82-6	N		
Brewer Yeast	84604-16-0	N		
Egg Flavor		N		
Chicken Flavor		N		
Soybean Oil	8001-22-7	N		
Corn Starch		N		
Liver Powder		N		
Wheat Germ		N		
Sugar	57-50-1	N		
Dextrate	50-99-7	N		
Dextrate	39404-33-6	N		
Dextrate	68131-37-3	N		
Hydroxypropyl Methylcellulose Phthalate	9050-31-1	N		
Gelatin	9000-70-8	N		
Hydrolyzed Vegetable Protein		N		
Calcium Carbonate		N		
Calcium Phosphate Tribasic	7758-87-4	N		

Material	CAS Number	TAC ^A	Rule 226(a)(ii) ^B	Rule 225 ^C
Calcium Sulfate		N		
Cellulose Acetate	9004-35-7	N		
Cellulose, Powdered		N		
Citric Acid Monohydrate	5949-29-1	N		
Dextrose (Corn Sugar & Starch Sugar)		N		
Ethylcellulose	9004-57-3	N		
Fructose		N		
Glucose Liquid	8027-56-3	N		
Hydroxyethyl cellulose	9004-62-0	N		
Maltodextrin	9050-36-6	N		
Mannitol	69-65-8	N		
Starch - Pregelatinized	9005-25-8	N		
Starch - Sterilizable		N		
Sucrose	57-50-1	N		
Compressible Sugar	64294-03-7	N		
Compressible Sugar	66748-03-6	N		
Confectioner's Sugar	57-50-1, 9005-25-8	N		
Sugar Spheres		N		
Microcrystalline Wax	63231-60-7	N		
Corn syrup		N		

- ^A Indicates an AQD determination on whether the material is a toxic air contaminant (TAC):
- “Y” indicates the material is a TAC.
 - “N” indicates the material is not a TAC.
- ^B Indicates an AQD determination on whether the material meets the criteria of Rule 226(a)(ii):
- “Y” indicates the material is not a carcinogen and is not listed in Table 20.
 - “N” indicates the material is a carcinogen or is listed in Table 20, or both.
 - If there is no entry in this column for a material, the AQD made no determination.
- ^C Indicates an AQD determination on whether the emission rate for the material the applicant provided to the AQD met the requirement of Rule 225(1).
- “Y” indicates the AQD made this determination for the material.
 - If there is no entry in this column for a material, the AQD made no determination.
- ^D Applies to an AQD determination that a material is a TAC, as in note A above. The AQD has not established a screening level for any TAC with this note, but has determined that in lieu of setting a screening level, the primary NAAQS for particulate matter (PM_{2.5}, PM₁₀) are reasonable and appropriate health protective levels for the particulate. The AQD considered the combined ambient impact of all particulate TAC emissions from the process in the review of PTI No. 73-17B.