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

October 6, 2023

PERMIT TO INSTALL 73-17D

> 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 REQ | UIRED BY RULE 203: |  |  |  |  |  |
|--|--------------------|--|--|--|--|--|
| August 28, 2023                        |                    |  |  |  |  |  |
|  |                    |  |  |  |  |  |
| DATE PERMIT TO INSTALL APPROVED:       | SIGNATURE:         |  |  |  |  |  |
| October 06, 2023                       |                    |  |  |  |  |  |
|  |                    |  |  |  |  |  |
| DATE PERMIT VOIDED:                    | SIGNATURE:         |  |  |  |  |  |
|  |                    |  |  |  |  |  |
|  |                    |  |  |  |  |  |
| DATE PERMIT REVOKED:                   | SIGNATURE:         |  |  |  |  |  |
|  |                    |  |  |  |  |  |
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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

IRSLInitial Risk Screening LevelITSLInitial Threshold Screening LevelLAERLowest Achievable Emission RateMACTMaximum Achievable Control TechnologyMAERSMichigan 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

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

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#### **POLLUTANT / MEASUREMENT ABBREVIATIONS**

acfm Actual cubic feet per minute

BTU British Thermal Unit 
°C Degrees Celsius 
CO Carbon Monoxide

CO2e Carbon Dioxide Equivalent dscf Dry standard cubic foot dscm Dry standard cubic meter Personal Per

gr Grains

HAP Hazardous Air Pollutant

Hg Mercury hr Hour

HP Horsepower 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 absolute psig Pounds per square inch gauge

scf Standard cubic feet

 $\begin{array}{ccc} \text{sec} & & \text{Seconds} \\ \text{SO}_2 & & \text{Sulfur Dioxide} \end{array}$ 

TAC Toxic Air Contaminant

Temp Temperature

THC Total Hydrocarbons tpy Tons per year Microgram

µm Micrometer or Micron

VOC Volatile Organic Compounds

yr Year

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#### **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.

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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)
- 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)

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## **EMISSION UNIT SPECIAL CONDITIONS**

#### **EMISSION UNIT SUMMARY TABLE**

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

|  | Emission Unit Description  |                   |  |  |  |  |
|--|--|-------------------|--|--|--|--|
| Emission Unit ID   | (Including Process Equipment & Control Device(s))  | Flexible Group ID |  |  |  |  |
| EUPilotFBGD  | Pilot scale batch fluidized bed granulator dryer   | NA .              |  |  |  |  |
|  | (FBGD). Maximum batch size is 60 kilograms.  |                   |  |  |  |  |
|  | Emissions are exhausted to DUST5120-1 followed   |                   |  |  |  |  |
|  | by a HEPA filter.  |                   |  |  |  |  |
| EUB248WeighA   | Building 248 Oral Solid Dosage (OSD) weighing area   | FGB248OSD         |  |  |  |  |
| , and the second | A. Emissions are exhausted to DUST4300-2   |                   |  |  |  |  |
|  | followed by a HEPA filter and also vented inside the   |                   |  |  |  |  |
|  | building in downflow booth with HEPA control.  |                   |  |  |  |  |
| EUB248L1Blend  | Building 248 OSD Line 1 blending, mechanical   | FGB248OSD         |  |  |  |  |
|  | processing, and dispensing. Emissions are  |                   |  |  |  |  |
|  | exhausted through local exhaust ventilation to   |                   |  |  |  |  |
|  | DUST4300-2 followed by a HEPA filter.  |                   |  |  |  |  |
| EUB248L1Tablet   | Building 248 OSD Line 1 tablet compression.  | FGB248OSD         |  |  |  |  |
|  | Emissions are exhausted to DUST4300-1 followed   |                   |  |  |  |  |
|  | by a HEPA filter or DUST4300-4 followed by a HEPA  |                   |  |  |  |  |
|  | filter.  |                   |  |  |  |  |
| EUB248L1TabCoat  | Building 248 OSD Line 1 tablet coating (aqueous).  | FGB248OSD         |  |  |  |  |
|  | Emissions are exhausted to DUST4340-1 followed   |                   |  |  |  |  |
|  | by a HEPA filter and local exhaust ventilation to  |                   |  |  |  |  |
| FUD2400CDDka   | DUST4300-2 followed by a HEPA filter.  | FCD040CCD         |  |  |  |  |
| EUB248OSDPkg   | Building 248 OSD packaging. Emissions are  | FGB248OSD         |  |  |  |  |
|  | exhausted either to DCOSDPACK, which vents inside the building, or to DUST4300-5 followed by a |                   |  |  |  |  |
|  | HEPA filter.   |                   |  |  |  |  |
| EUB248L2Blend  | Building 248 OSD Line 2 blending, mechanical   | FGB248OSD         |  |  |  |  |
| LOBZ-OLZBICHO  | processing, and dispensing. Emissions are  | 1 00240000        |  |  |  |  |
|  | exhausted to DUST4300-5 followed by a HEPA filter.   |                   |  |  |  |  |
| EUB248L2HSG  | Building 248 OSD Line 2 high shear granulation.  | FGB248OSD         |  |  |  |  |
|  | Emissions are exhausted to HEPA1114560. Local  |                   |  |  |  |  |
|  | exhaust ventilation system to DUST4300-5 followed  |                   |  |  |  |  |
|  | by a HEPA filter.  |                   |  |  |  |  |
| EUB248L2FBGDAq   | Building 248 OSD Line 2 aqueous fluidized bed  | FGB248OSD         |  |  |  |  |
| ·  | granulator dryer. Emissions are exhausted to   |                   |  |  |  |  |
|  | HEPA1111765. Local exhaust ventilation system to   |                   |  |  |  |  |
|  | DUST4300-5 followed by a HEPA filter.  |                   |  |  |  |  |
| EUB248L3Blend  | Building 248 OSD Line 3 blending, mechanical   | FGB248OSD         |  |  |  |  |
|  | processing, and dispensing. Emissions are  |                   |  |  |  |  |
|  | exhausted to DUST4300-3 followed by a HEPA filter.   |                   |  |  |  |  |
| EUB248L3HSG  | Building 248 OSD Line 3 high shear granulation.  | FGB248OSD         |  |  |  |  |
|  | Emissions are exhausted to HEPAF241630. Local  |                   |  |  |  |  |
|  | exhaust ventilation system to DUST4300-3 followed  |                   |  |  |  |  |
|  | by a HEPA filter.  |                   |  |  |  |  |

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| Emission Unit ID | Emission Unit Description<br>(Including Process Equipment & Control Device(s))   | Flexible Group ID |
|------------------|--|-------------------|
| EUB248L3FBGDAq   | Building 248 OSD Line 3 aqueous fluidized bed granulator dryer and associated conveying system. Emissions are exhausted to HEPAFILT4370-B9 and HEPAB248L3AqPCS. Local exhaust ventilation system to DUST4300-3 followed by a HEPA filter.                                    | FGB248OSD         |
| EUB248L3FBGDSol  | Building 248 OSD Line 3 solvent fluidized bed granulator dryer and associated conveying system. Emissions are exhausted to HEPAFILT4371-25 followed by the thermal oxidizer, and HEPAB248L3SOLPCS. Local exhaust ventilation system to DUST4300-3 followed by a HEPA filter. | FGB248OSD         |
| EUB248WeighB     | Building 248 OSD weighing area B. Emissions are exhausted to DUST4300-4 followed by a HEPA filter 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 DUST4300-4 followed by a HEPA filter.   | FGB248OSD         |
| EUB248L2&3TabB   | Building 248 OSD Lines 2 and 3 tablet compression unit B. Emissions are exhausted to DUST4300-4 followed by a HEPA filter.   | FGB248OSD         |
| EUB248L2&3TabC   | Building 248 OSD Lines 2 and 3 tablet compression unit C. Emissions are exhausted to DUST4300-4 followed by a HEPA filter.   | 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.

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# EUPIIotFBGD 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 /<br>Operating Scenario  | Equipment   | Monitoring /<br>Testing<br>Method | Underlying<br>Applicable<br>Requirements |
|-----------------|-------------|--|-------------|-----------------------------------|--|
| 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,<br>R 336.1702(a)             |
| 2. PM           | 0.003 lb/hr | Hourly   | EUPilotFBGD | SC VI.5                           | R 336.1224,<br>R 336.1225,<br>R 336.1331 |

## II. MATERIAL LIMIT(S)

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

<sup>&</sup>quot;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)

- 1. The permittee shall not operate EUPilotFBGD unless a malfunction abatement plan (MAP) as described in Rule 911(2), for EUPilotFBGD, has been submitted within 180 days of permit issuance, and is implemented and maintained. The MAP shall, at a minimum, specify the following:
  - a) A complete preventative maintenance program including identification of the supervisory personnel responsible for overseeing the inspection, maintenance, and repair of air-cleaning devices, a description of the items or conditions that shall be inspected, the frequency of the inspections or repairs, and an identification of the major replacement parts that shall be maintained in inventory for quick replacement.

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b) An identification of the source and air-cleaning device operating variables that shall be monitored to detect a malfunction or failure, the normal operating range of these variables, and a description of the method of monitoring or surveillance procedures.

c) A description of the corrective procedures or operational changes that shall be taken in the event of a malfunction or failure to achieve compliance with the applicable emission limits.

If at any time the MAP fails to address or inadequately addresses an event that meets the characteristics of a malfunction, the permittee shall amend the MAP within 45 days after such an event occurs. The permittee shall also amend the MAP within 45 days, if new equipment is installed or upon request from the District Supervisor. The permittee shall submit the MAP and any amendments to the MAP to the AQD District Supervisor for review and approval. If the AQD does not notify the permittee within 90 days of submittal, the MAP or amended MAP shall be considered approved. Until an amended plan is approved, the permittee shall implement corrective procedures or operational changes to achieve compliance with all applicable emission limits. (R 336.1225, R 336.1331, R 336.1702(a), R 336.1910, R 336.1911, R 336.2803, R 336.2804, 40 CFR 52.21(c) and (d))

### IV. <u>DESIGN/EQUIPMENT PARAMETER(S)</u>

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. The permittee shall keep a record of each visible emissions check and maintenance conducted to eliminate visible emissions. 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 336.1910)

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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. (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.<sup>1</sup> (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.<sup>1</sup> (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: (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.

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## 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<br>Above Ground<br>(feet) | Underlying Applicable<br>Requirements |
|--|--|--|---------------------------------------|
| SV-DUST5120-1     (Fluid Bed Granulator     Dryer [Pilot Plant]) | 14   | 32                                       | 40 CFR 52.21(c) & (d)                 |

## IX. OTHER REQUIREMENT(S)

NA

#### Footnotes:

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

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## **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<br>Emission Unit IDs |
|-------------------|---|---------------------------------|
| FGB248OSD         | The Lines 1, 2, and 3 OSD manufacturing equipment in    | EUB248WeighA,                   |
|                   | Building 248, including the Line 2 and Line 3 fluidized | EUB248WeighB,                   |
|                   | bed granulator dryers.                                  | EUB248L1Blend,                  |
|                   |   | EUB248L2Blend,                  |
|                   |   | EUB248L3Blend,                  |
|                   |   | EUB248L2HSG,                    |
|                   |   | EUB248L3HSG,                    |
|                   |   | EUB248L2FBGDAq,                 |
|                   |   | EUB248L3FBGDAq,                 |
|                   |   | EUB248L3FBGDSol,                |
|                   |   | EUB248L1Tablet,                 |
|                   |   | EUB248L1TabCoat,                |
|                   |   | EUB248L2&3TabA,                 |
|                   |   | EUB248L2&3TabB,                 |
|                   |   | EUB248L2&3TabC,                 |
|                   |   | EUB248OSDPkg                    |

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# FGB248-OSD 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

Fourteen 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)
- DUST4300-5 (dust collector followed by HEPA filter)
- DUST4300-3 (dust collector followed by HEPA filter)
- HEPA111765 (HEPA filter only)
- HEPAB248L3AqPCS (HEPA filter only)
- HEPAB2483SoIPSC (HEPA filter only)
- HEPA1114560 (HEPA filter only)
- HEPAF241630 (HEPA filter only)
- DUST4300-4 (dust collector followed by HEPA filter)
- HEPAFILT4370-B9
- Thermal oxidizer following HEPAFILT4371-25

#### I. EMISSION LIMIT(S)

| Pollutant                                      | Limit                                  | Time Period / Operating Scenario   | Equipment       | Monitoring /<br>Testing<br>Method | Underlying<br>Applicable<br>Requirements |
|--|--|--|-----------------|-----------------------------------|--|
| 1. VOC   | 8.9 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   | 6.3 lb/hr                              | Hourly   | EUB248L3FBGDSol | SC VI.4                           | R 336.1702(a)                            |
| 3. Each<br>Category<br>226(a) TAC <sup>A</sup> | Less than 10<br>lbs/month <sup>1</sup> | Calendar month   | FGB248OSD       | SC VI.8                           | R 336.1225,<br>R 336.1226(a)             |
| 4. Each<br>Category<br>226(a) TAC              | Less than<br>0.14 lb/hr <sup>1</sup>   | Hourly   | FGB248OSD       | SC IV.1, VI.6                     | R 336.1225,<br>R 336.1226(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

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#### II. MATERIAL LIMIT(S)

|    |                        |                    | Time Period / Operating  |           | Monitoring /<br>Testing | Underlying<br>Applicable |
|----|------------------------|--------------------|--------------------------|-----------|-------------------------|--------------------------|
|    | Material               | Limit              | Scenario                 | Equipment | Method                  | Requirements             |
| 1. | Total material         | 214,300 lbs per    | Calendar month           | FGB248OSD | SC VI.6                 | R 336.1225,              |
|    | processed <sup>A</sup> | month <sup>1</sup> |                          | batches   |                         | R 336.1226(a)            |
| 2. | Total API              | 29,900 lbs per     | Calendar month           | FGB248OSD | SC VI.6                 | R 336.1225,              |
|    | material <sup>B</sup>  | month <sup>1</sup> |                          | batches   |                         | R 336.1226(a)            |
|    | processed              |                    |                          |           |                         |                          |
| 3. | Total organic          | 8,800 lbs per      | 12-month rolling time    | FGB248OSD | SC VI.2                 | R 336.1702(a)            |
|    | cleaning solvent       | year               | period as determined at  |           |                         |                          |
|    | use                    |                    | the end of each calendar |           |                         |                          |
|    |                        |                    | month                    |           |                         |                          |

<sup>&</sup>lt;sup>A</sup> "Total material processed" does not include coating materials.

#### 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 operate FGB248OSD unless a malfunction abatement plan (MAP) as described in Rule 911(2), for FGB248OSD, has been submitted within 180 days of permit issuance, and is implemented and maintained. The MAP shall, at a minimum, specify the following:
  - a) A complete preventative maintenance program including identification of the supervisory personnel responsible for overseeing the inspection, maintenance, and repair of air-cleaning devices, a description of the items or conditions that shall be inspected, the frequency of the inspections or repairs, and an identification of the major replacement parts that shall be maintained in inventory for guick replacement.
  - b) An identification of the source and air-cleaning device operating variables that shall be monitored to detect a malfunction or failure, the normal operating range of these variables, and a description of the method of monitoring or surveillance procedures.
  - c) A description of the corrective procedures or operational changes that shall be taken in the event of a malfunction or failure to achieve compliance with the applicable emission limits.

If at any time the MAP fails to address or inadequately addresses an event that meets the characteristics of a malfunction, the permittee shall amend the MAP within 45 days after such an event occurs. The permittee shall also amend the MAP within 45 days, if new equipment is installed or upon request from the District Supervisor. The permittee shall submit the MAP and any amendments to the MAP to the AQD District Supervisor for review and approval. If the AQD does not notify the permittee within 90 days of submittal, the MAP or amended MAP shall be considered approved. Until an amended plan is approved, the permittee shall implement corrective procedures or operational changes to achieve compliance with all applicable emission limits. (R 336.1225, R 336.1331, R 336.1702(a), R 336.1910, R 336.1911, R 336.2803, R 336.2804, 40 CFR 52.21(c) and (d))

#### IV. <u>DESIGN/EQUIPMENT PARAMETER(S)</u>

- 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)

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

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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. The permittee shall keep a record of each visible emissions check and maintenance conducted to eliminate visible emissions. 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 336.1910)
  - a) DUST4300-2
  - b) DUST4300-1
  - c) DUST4340-1
  - d) DCOSDPACK
  - e) DUST4300-5
  - f) HEPA111765
  - g) HEPAB248L3AqPCS
  - h) HEPAB248L3SoIPCS
  - i) HEPAFILT4370-B9
  - j) HEPAFILT4371-25
  - k) DUST4300-4
  - I) DUST4300-3
  - m) HEPA1114560
  - n) HEPAF241630

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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.<sup>1</sup> (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.1, the permittee shall follow the procedure below.<sup>1</sup> (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:
    - . 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.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 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. (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:
    - . 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))

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## VII. REPORTING

1. 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:

|                             | Maximum Exhaust Diameter / Dimensions | Minimum Height Above Ground | Underlying<br>Applicable |
|-----------------------------|---------------------------------------|-----------------------------|--------------------------|
| Stack & Vent ID             | (inches)                              | (feet)                      | Requirements             |
| 1. SV-DUST4340-1            | 26                                    | 28                          | R 336.1225,              |
| (OSD Line 1 Coating Dust    |                                       |                             | 40 CFR 52.21(c) & (d)    |
| Collector)                  |                                       |                             |                          |
| 2. SV-DUST4300-2            | 16                                    | 28                          | R 336.1225,              |
| (OSD Line 1 Blending/Tablet |                                       |                             | 40 CFR 52.21(c) & (d)    |
| Coating & Weigh A Dust      |                                       |                             |                          |
| Collector)                  |                                       |                             |                          |
| 3. SV-DUST4300-1            | 14                                    | 28                          | R 336.1225,              |
| (OSD Line 1 Tableting Dust  |                                       |                             | 40 CFR 52.21(c) & (d)    |
| Collector)                  |                                       |                             |                          |
| 4. SV-DUST4300-5            | 20                                    | 60                          | R 336.1225,              |
| (OSD Line 2 Dust Collector) |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 5. SV-DUST4300-3            | 20                                    | 60                          | R 336.1225,              |
| (OSD Line 3 & Weigh B Dust  |                                       |                             | 40 CFR 52.21(c)&(d)      |
| Collector)                  |                                       |                             |                          |
| 6. SV-DUST4300-4            | 20                                    | 60                          | R 336.1225,              |
| (OSD Lines 1, 2, and 3      |                                       |                             | 40 CFR 52.21(c)&(d)      |
| Tableting Dust Collector)   |                                       |                             |                          |
| 7. SV-L2FBGDAq              | 24                                    | 60                          | R 336.1225,              |
| (OSD Line 2 aqueous FBGD)   |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 8. HEPAB248L3AqPCS          | 4                                     | 50                          | R 336.1225,              |
| (OSD Line 3 aqueous FBGD)*  |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 9. SV-FANE4370              | 20                                    | 60                          | R 336.1225,              |
| (OSD Line 3 solvent FBGD)   |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 10.SV- HEPAB248L3SoIPCS     | 4                                     | 50                          | R 336.1225,              |
| (OSD Line 3 solvent FBGD)*  |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 11.SV-FANE4371              | 18 × 18 <sup>A</sup>                  | 25                          | R 336.1225,              |
| (OSD Line 3 solvent FBGD)   |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 12.SV-L2HSGHEPA             | 4                                     | 50                          | R 336.1225,              |
| (OSD Line 2 HSG)*           |                                       |                             | 40 CFR 52.21(c)&(d)      |
| 13.SV-L3HSGHEPA             | 4                                     | 50                          | R 336.1225,              |
| (OSD Line 3 HSG)*           |                                       |                             | 40 CFR 52.21(c)&(d)      |

<sup>\*</sup> This stack is not required to be discharged unobstructed vertically upwards

A Or other dimensions with a maximum interior horizontal cross-section area of 324 square inches.

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## IX. OTHER REQUIREMENT(S)

NA

#### Footnotes:

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

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#### 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   | TACA | Rule<br>226(a)(ii) <sup>B</sup> | Rule 225 <sup>c</sup> |
|---|--------------|------|---------------------------------|-----------------------|
| Magnesium stearate                        | 557-04-0     | Υ    | Y                               | Υ                     |
| 2,6-Di-tert-butyl-p-cresol                | 128-37-0     | Y    | N                               | Υ                     |
|   | 112926-00-8  |      |                                 |                       |
| Colloidal silicon dioxide                 | 112945-52-5  | Υ    | Y                               | Υ                     |
|   | 7631-86-9    |      |                                 |                       |
| Fumed silica                              | 60676-86-0   | Υ    | Y                               | Υ                     |
| Talc                                      | 14807-96-6   | Y    | N                               | Y                     |
| Carboxymethylcellulose sodium             | 9004-32-4    | Υ    | Y                               | Υ                     |
| Diethyl phthalate                         | 84-66-2      | Υ    | Y                               | Υ                     |
| Glycerin/glycerol                         | 56-81-5      | Υ    | Υ                               | Υ                     |
| Poloxamer                                 | 9003-11-6    | Υ    | Y                               | Υ                     |
| Polyethylene glycol                       | 25322-68-3   | Υ    | Υ                               | Υ                     |
| Povidone                                  | 9003-39-8    | Υ    | Υ                               | Υ                     |
| Titanium dioxide                          | 13463-67-7   | Υ    | Υ                               | Υ                     |
| Triacetin                                 | 102-76-1     | Υ    | Y                               | Υ                     |
| Triethyl citrate                          | 77-93-0      | Υ    | Y                               | Υ                     |
| Sulfuric acid                             | 7664-93-9    | Y    |                                 | Υ                     |
| Isopropyl alcohol                         | 67-63-0      | Υ    | Y                               | Υ                     |
| Ethyl alcohol                             | 64-17-5      | Υ    | Y                               | Υ                     |
| Amorphous Silica                          | 112926-00-8  | Υ    | Υ                               | Υ                     |
| Acetone                                   | 67-64-1      | Υ    | Υ                               | Υ                     |
| Carprofen                                 | 53716-49-7   | Y    | Υ                               |                       |
| Ivermectin                                | 70288-86-7   | Y    | Υ                               |                       |
| 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                               | 1                     |
| Cellulose Acetate Phthalate               | 9004-38-0    | Y    | Y                               |                       |
| Polymethacrylates                         | 9010-88-2    | Y    | Y                               |                       |
| Polymethacrylates                         | 24938-16-7   | Y    | Y                               | 1                     |
| Polymethacrylates                         | 25086-15-1   | Y    | Y                               | 1                     |
| Polymethacrylates                         | 33434-24-1   | Y    | Y                               |                       |

| Material  | CAS Number              | TACA | Rule<br>226(a)(ii) <sup>B</sup> | Rule 225 <sup>c</sup> |
|---|-------------------------|------|---------------------------------|-----------------------|
| Cyclodextrin  | 7585-39-9               | Y    | Υ                               |                       |
| FD&C Blue #2  | 860-22-0<br>16521-38-3  | Y    | Υ                               |                       |
| Ponceau 4R  | 2611-82-7               | Υ    | Y                               |                       |
| FD&C Yellow #6  | 2783-94-0<br>15790-07-5 | Υ    | Υ                               |                       |
| Carboxymethylcellulose calcium  | 9050-04-8               | Y    | Υ                               |                       |
| Butylated hydroxyanisole  | 25013-16-5              | ΥD   | •                               |                       |
| Calcium phosphate dibasic, anhydrous  | 7757-93-9               | ΥD   |                                 |                       |
| Hydroxy Propyl Methyl Cellulose   | 9004-65-3               | ΥD   |                                 |                       |
| Sodium Chloride   | 7647-14-5               | ΥD   |                                 |                       |
| Polysorbate 80  | 9005-65-6               | ΥD   |                                 |                       |
| Polyvinyl alcohol (polymer)   | 9002-89-5               | ΥD   |                                 |                       |
| Monosodium phosphate  | 7558-80-7               | ΥD   |                                 |                       |
| Polydextrose  | 68424-04-4              | ΥD   |                                 |                       |
| Hydroxy Propyl Cellulose  | 9004-64-2               | ΥD   |                                 |                       |
| Croscarmellose Sodium   | 74811-65-7              | ΥD   |                                 |                       |
| Disodium EDTA   | 6381-92-6               | Y    | Y                               |                       |
| Meglumine   | 6284-40-8               | Y    | Y                               |                       |
| FD&C Blue #1  | 3844-45-9               | Y    | Y                               |                       |
|   | 25956-17-6              |      |                                 |                       |
| FD&C Red #40  | 68583-95-9              | Y    | Υ                               |                       |
| Microcrystalline Cellulose  | 9004-34-6               | N    |                                 |                       |
|   | 5989-81-1               |      |                                 |                       |
| Lactose Monohydrate   | 64044-51-5              | N    |                                 |                       |
| _acicco inchen, arate   | 63-42-3                 |      |                                 |                       |
| 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  | 1000 07 1               | N    |                                 |                       |
| Sodium Starch Glycolate   | 9063-38-1               | N    |                                 |                       |
| Medium Chain Triglycerides  | 3000 00 1               | N    |                                 |                       |
| Glycerol Mono-Stearate  | 31566-31-1              | N    |                                 |                       |
| Xanthan Gum   | 11138-66-2              | N    |                                 |                       |
| AFB Palatant (includes 10% sodium sulfate)  | 11100 00 2              | N    |                                 |                       |
| Sodium Sulfate  | 7757-82-6               | N    |                                 |                       |
| Brewer Yeast  | 84604-16-0              | N    |                                 |                       |
| Egg Flavor  | 3.551.155               | N    |                                 |                       |
| Chicken Flavor  |                         | N    |                                 | 1                     |
| Soybean Oil   | 8001-22-7               | N    |                                 | 1                     |
| Corn Starch   | 333. 22 /               | N    |                                 | 1                     |
| Liver Powder  |                         | N    |                                 |                       |
| Wheat Germ  |                         | N    |                                 | 1                     |
| Sugar   | 57-50-1                 | N    |                                 | 1                     |
| Dextrate  | 50-99-7                 | N    |                                 | 1                     |
| Dextrate  | 39404-33-6              | N    |                                 |                       |
| Dextrate  | 68131-37-3              | N    |                                 | 1                     |
| Hydroxypropyl Methylcellulose Phthalate   | 9050-31-1               | N    |                                 | +                     |
| Gelatin   | 9000-70-8               | N    |                                 | 1                     |
| Guadii  | 3000-70-0               | N    |                                 |                       |

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| Material                             | CAS Number           | TACA | Rule<br>226(a)(ii) <sup>B</sup> | Rule 225 <sup>c</sup> |
|--------------------------------------|----------------------|------|---------------------------------|-----------------------|
| 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<br>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.
- 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.
- 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.
- 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.

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#### 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                           | TACA | Rule<br>226(a)(ii) <sup>B</sup> | Rule 225 <sup>c</sup> |
|---|--------------------------------------|------|---------------------------------|-----------------------|
| Magnesium stearate  | 557-04-0                             | Y    |                                 | Υ                     |
| Butylated hydroxytoluene  | 128-37-0                             | Y    |                                 | Υ                     |
| Colloidal silicon dioxide   | 112926-00-8,<br>112945-52-5          | Y    |                                 | Υ                     |
| Colloidal silicon dioxide   | 7631-86-9                            | Υ    | N                               | Υ                     |
| Glycerin/glycerol   | 56-81-5                              | Υ    |                                 | Υ                     |
| Polyethylene glycol   | 25322-68-3                           | Υ    |                                 | Υ                     |
| Povidone  | 9003-39-8                            | Υ    |                                 | Υ                     |
| Titanium dioxide  | 13463-67-7                           | Υ    |                                 | Υ                     |
| Isopropyl alcohol   | 67-63-0                              | Y    |                                 | Υ                     |
| Ethyl alcohol   | 64-17-5                              | Y    |                                 | Υ                     |
| Oclacitinib maleate   | 1208319-27-0                         | Υ    | Υ                               |                       |
| Moxidectin  | 113507-06-5                          | Υ    | Υ                               |                       |
| Pyrantel pamoate  | 22204-24-6                           | Y    | Υ                               |                       |
| Sarolaner   | 1398609-39-6                         | Y    | Υ                               |                       |
| FD&C Blue #2  | 860-22-0                             | Y    | Υ                               |                       |
| FD&C Blue #2  | 16521-38-3                           | Y    | Υ                               |                       |
| FD&C Yellow #6  | 2783-94-0                            | Y    | Υ                               |                       |
| FD&C Yellow #6  | 15790-07-5                           | ΥD   | Υ                               |                       |
| Hydroxy Propyl Methyl Cellulose   | 9004-65-3                            | ΥD   | Y                               |                       |
| Sodium Chloride   | 7647-14-5                            | ΥD   | Υ                               |                       |
| Hydroxy Propyl Cellulose  | 9004-64-2                            | ΥD   | Υ                               |                       |
| Disodium EDTA   | 6381-92-6                            | ΥD   | Υ                               |                       |
| Meglumine   | 6284-40-8                            | Υ    | N                               | Υ                     |
| FD&C Red #40  | 25956-17-6                           | ΥD   | Υ                               |                       |
| FD&C Red #40  | 68583-95-9                           | ΥD   | Υ                               |                       |
| Microcrystalline Cellulose  | 9004-34-6                            | N    |                                 |                       |
| Lactose Monohydrate   | 5989-81-1,<br>64044-51-5,<br>63-42-3 | N    |                                 |                       |
| Palatable Base Granules (consisting of sugar;<br>maize starch; and calcium phosphate<br>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    |                                 |                       |
| Sodium Starch Glycolate   | 9063-38-1                            | N    |                                 |                       |
| Glycerol Mono-Stearate  | 31566-31-1                           | N    |                                 |                       |
| Xanthan Gum   | 11138-66-2                           | N    |                                 |                       |
| Brewer Yeast  | 84604-16-0                           | N    |                                 |                       |
| Liver Powder  |                                      | N    |                                 |                       |

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<sup>&</sup>quot;Y" indicates the material is a TAC.

 <sup>&</sup>quot;N" indicates the material is not a TAC.

Indicates an AQD determination on whether the material meets the criteria of Rule 226(a)(ii):

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- "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.
- 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.
- 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. 73-17B.