REGULATION III – CONTROL OF AIR CONTAMINANTS

RULE 349
PHARMACEUTICAL, COSMETIC AND VITAMIN MANUFACTURING OPERATIONS

INDEX

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MARICOPA COUNTY
AIR POLLUTION CONTROL REGULATIONS

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SECTION 100 – GENERAL

101 PURPOSE: To limit the emission of volatile organic compounds from pharmaceutical, cosmetic and vitamin manufacturing operations.

102 APPLICABILITY: The provisions of this rule shall apply to the manufacture and/or blending of materials to make pharmaceutical, or cosmetic products or vitamins, including any process that is incidental to such operations, such as tablet coating and finishing.

SECTION 200 – DEFINITIONS: For the purpose of this rule, the following definitions shall apply, in addition to those definitions found in Rule 100 (General Provisions and Definitions) of these rules. In the event of any inconsistency between any of the Maricopa County air pollution control rules, the definitions in this rule take precedence.

201 COATING: A film or thin layer applied to a base material called a substrate.

202 CONDENSER: A device that cools a gas stream to a temperature which removes specific organic compounds by condensation.

203 COSMETIC PRODUCTS: Any material described by the Standard Industrial Classification (SIC) Code 284, as incorporated by reference in subsection 502.1 of this rule.

204 COSMETICS MANUFACTURING FACILITY: Any plant producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetic products.

205 EMISSION CONTROL SYSTEM (ECS): A system for reducing emissions of organic compounds, consisting of both emissions collection and processing devices which are approved in writing by the Control Officer and are designed and operated in accordance with good engineering practice.

206 EXEMPT COMPOUNDS: For the purpose of this rule, the non-VOC, non-aqueous evaporating portion of a formulation; this necessarily includes all non-precursor organic compounds in addition to inorganic liquids and gases.

207 **IN-PROCESS TANK:** Containers used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals, cosmetics or vitamins.

208 **PHARMACEUTICAL MANUFACTURING FACILITY:** Any plant producing or blending chemicals for use in pharmaceutical products and/or employing chemical processes in the manufacture of pharmaceutical products. This definition includes any and all associated storage tanks, wastewater management units, or components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

209 **PHARMACEUTICAL PRODUCTS:** Any material described by the Standard Industrial Classification (SIC) Code 283, as incorporated by reference in subsection 502.1 of this rule, or any other fermentation, biological or natural extraction, or chemical synthesis product regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product.

210 **REACTOR:** A device or vessel in which one or more chemicals or reactants, other than air, are combined or decomposed in such a way that their molecular structures are altered and one or more new organic compounds are formed.

211 **TOTAL VOC-VAPOR PRESSURE (VOC COMPOSITE PARTIAL PRESSURE):** The sum of the partial pressures of the compounds defined as VOCs calculated according to the formula in Section 504 of this rule.

SECTION 300 – STANDARDS:

301 **REACTORS, DISTILLATION COLUMNS, CRYSTALLIZERS & CENTRIFUGES:** No person shall emit more than 6.8 kg (15 lbs) of VOC compounds per day from any reactor, distillation column, crystallizer or centrifuge unless such emissions are reduced by one of the following:

301.1 Surface Condensers designed to reduce VOC emissions and having the outlet gas temperature limited as follows:

TABLE 1

Vapor Pressure of VOC Compounds at 20° C (68° F)	Maximum Condenser Outlet Gas Temp. ° C (°F)
26-52 mmHg (0.5 psi to 1.0 psi)	25 (77)
52-78 mmHg (1.0 psi to 1.5 psi)	10 (50)
78-150 mmHg (1.5 psi to 2.9 psi)	0 (32)
150-300 mmHg (2.9 psi to 5.8 psi)	-15 (5)
over 300 mmHg (over 5.8 psi)	-25 (-13)

301.2 Any other emission control system which is approved in writing by the control officer as having a control efficiency greater than or equal to surface condenser efficiency operated in accordance with subsection 301.1 of this rule.

302 IN-PROCESS TANKS: No person shall use any in-process tank(s) for material containing VOC unless it is fitted with a cover or other device provided for the tank which prevents VOC evaporation. The cover or device shall be closed or in place on the tank at all times except during loading or unloading of the tank.

303 SEPARATION OPERATIONS: No person shall emit more than 15 kg (33 lbs) or more of VOC compounds per day from any rotary vacuum filter or any other filter or separation device having an exposed liquid surface where the liquid contains organic compounds with a "Total VOC-Vapor Pressure" of 26 mm Hg (0.5 psia) or more at 20°C (68° F) unless such emissions are reduced by 90 percent on a mass basis.

304 STERILIZERS: No person shall emit 15 kg (33 lbs) or more per day of VOCs from any chemical sterilizer unless such emissions are reduced by at least 75 percent on a mass basis.

305 AIR DRYERS: No person shall emit 15 kg (33 lbs) or more of VOCs per day from any air dryer unless such emissions are reduced by at least 90 percent by weight.

306 TABLET COATING

306.1 Limitation–VOC Emissions: No person shall apply any coating to a pharmaceutical tablet with a VOC content in excess of 3.5 pounds of VOC per gallon of coating applied (420 g/l), excluding water, unless the emissions are controlled in accordance with the provision of subsection 306.2.

306.2 Emission Control System: As an alternative to meeting the coating limit in subsection 306.1, an owner or operator may comply with this rule by operating an Emissions Control System (ECS) approved by the Control Officer. The ECS shall meet the specifications of either one of the following:

a. The ECS shall have a combined VOC emissions capture and control equipment efficiency of at least 81% by weight, or

b. The ECS shall consist of a surface condenser operated with the outlet gas temperature as specified in Table 1 of subsection 301.1 of this rule.

307 BULK LOADING: A person shall not transfer volatile organic liquids having vapor pressures greater than 212 mm Hg (4.1 psia) at 20°C (68° F) from any rail car or tank truck into any storage tank with a capacity greater than 7,500 liters (2,000 gal.) unless organic compound emissions during transfer are reduced by 90 percent by weight.

308 STORAGE TANKS: All storage tanks that store volatile organic liquids with a vapor pressure greater than 78 mm Hg (1.5 psia) at 20 °C (68° F) shall be equipped with pressure/vacuum vents set at a minimum + 2 mm Hg (+ 0.03 psia).

309 OPERATING REQUIREMENTS: An operator shall repair all leaks from which volatile organic liquids can be observed to be dripping or seeping. The repair shall be completed the first time the equipment is off-line for a period long enough to complete the repair. The nature of the repair should be recorded in the O&M Plan.

310 SURFACE PREPARATION AND CLEANUP SOLVENT:

310.1 A person shall use closed containers for the storage or disposal of cloth or paper used for solvent surface preparation and cleanup.

310.2 A person shall store fresh or spent solvent in closed containers.

311 STORAGE AND DISPOSAL OF VOC:

311.1 All storage of VOC-containing materials subject to evaporation, including the storage of waste solvent and waste solvent residues, shall at all times be in closed containers except when contents are added or removed.

311.2 Containers shall be legibly labeled with their contents.

312 REQUIREMENTS FOR AIR POLLUTION CONTROL EQUIPMENT:

312.1 Operation and Maintenance (O&M) Plan Required for ECS:

a. An owner or operator shall provide and maintain (an) O&M Plan(s) for any ECS, any other emission processing equipment, and any ECS monitoring devices that are used pursuant to this Rule 349 or to an air pollution control permit.

b. The owner or operator shall submit to the Control Officer for approval the O&M Plans of each ECS and each ECS monitoring device that is used pursuant to this rule.

312.2 Providing and Maintaining ECS Monitoring Devices: Any person incinerating, adsorbing, or otherwise processing VOC emissions pursuant to this rule shall provide, properly install and maintain in calibration, in good working order and in operation, devices described in the facility's O&M Plan that indicate temperatures, pressures, rates of flow, or other operating conditions necessary to determine if air pollution control equipment is functioning properly and is properly maintained.

312.3 O&M Plan Responsibility: An owner or operator of a facility that is required to have an O&M Plan pursuant to subsection 312.1 must fully comply with all O&M Plans that the owner or operator has submitted for

approval, but which have not yet been approved, unless notified otherwise by the Control Officer in writing.

313 EXEMPTIONS

313.1 Small Sources: Sections 301, 302 303, 304, 305 and 306 of this rule shall not apply to any one facility from which the total VOC emissions from all operations subject to this rule emits less than 15 pounds (6.8 kg) per day and less than two tons (1814 kg) per year of volatile organic compounds.

313.2 Condenser Temperature: If the operation of a condenser at the exit temperature specified in Table 1 of subsection 301.1 of this rule results in freezing and consequent plugging of the condenser, the allowable exit temperature may be raised to a maximum of 2°C above the freezing point of the volatile organic compound.

SECTION 400 – ADMINISTRATIVE REQUIREMENTS

401 COMPLIANCE SCHEDULE

401.1 Effective Date: Except as provided in this section, the provisions of this Rule 349 become effective on July 1, 1999. The owner or operator shall notify the Control Officer in writing by March 16, 1999, if an ECS in accordance with subsection 306.2 will be used to comply with this rule. The ECS shall be in use by December 16, 1999.

SECTION 500 – MONITORING AND RECORDS

501 RECORDKEEPING AND REPORTING: Records shall be retained for five years and shall be made available to the Control Officer upon request. Any person subject to this rule shall comply with the following requirements:

501.1 Current List

a. **Solvents:** Maintain a current list of solvents; state the VOC content of each in pounds per gallons or grams per liter. The VOC content of solvents and any liquids used as cleaning or degreasing agents shall be stated with exempt compounds such as water and non-precursors included.

b. **Vapor Pressure:** A facility subject to total VOC vapor-pressure limits shall have on site in one of the following forms the identified value of the total VOC vapor-pressure for each subject solvent being used: a manufacturer's technical data sheet, a manufacturer's safety data sheet (MSDS), or actual test results.

c. **Coatings:** Maintain a current list of coatings in use and the amount of VOCs applied.

501.2 Usage Records: Maintain monthly records showing the type and amount of each VOC containing material used and coatings applied except for materials arriving on-site with less than 2% VOC by weight.

502 COMPLIANCE DETERMINATION AND TEST METHODS: When more than one test method is permitted for determination, an exceedance of the limits by any of the applicable test methods constitutes a violation of this rule.

502.1 Compliance Determination: The following methods shall be used to determine compliance with this rule:

a. Measurement of VOC emissions from a control device shall be conducted in accordance with USEPA Test Method 25 or 25A (40 CFR 60, Appendix A). USEPA Test Method 18 shall be used to determine emissions of exempt compounds if the Control Officer requires that such determinations need to be made.

b. VOC content of materials having more than 10% solids by volume shall be determined using the applicable EPA Reference Method 24 or 24A (40 CFR Part 60, Appendix A). The Control Officer may use manufacturers' data sheets for routine and uncontested determination of VOC content.

c. The VOC content of solutions, dispersions, and emulsions that have no solids or less than 5% solids shall be determined by the April 15, 1992, amended Method 31 of California's Bay Area Air Quality Management District, "Determination of Volatile Organic Compounds in Paint Strippers, Solvent Cleaners, and Low Solids Coatings."

d. Solid-free solutions, in which all organic content is non-exempt and will certainly evaporate under Method 24 oven conditions, may be tested using the adaptation of EPA Method 415.1 as proposed by Sorrell, et. al. of EPA's Emission Measurement Center, Office of Air Quality Planning & Standards (OAQPS): "Total Organic Carbon for Offset Lithographic Solutions."

e. The VOC content of materials believed to have between 5 and 10% solids shall be determined by either EPA Method 24 or by Bay Area Method 31.

f. Total absolute vapor-pressure of solvents containing VOC shall be determined in accordance with ASTM Test Method D 2879-83, "Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope," 1983 edition.

g. Temperature measurements shall be done with an instrument having an accuracy and precision of no less than ± one (1) degree Celsius.

h. The U.S. Government Printing Office "Standard Industrial Classification Manual, 1987" (and no future editions) is incorporated by reference and is on file at the Maricopa County Air Quality Department, 1001 N. Central Ave., Phoenix, Arizona 85004.

502.2 Test Methods Adopted by Reference: The test methods for those subparts of 40 CFR Part 60, Appendix A, adopted as of July 1, 1998, as listed below, are adopted by reference. The other test methods listed in subsection 502.2 are referred to by their specific dates of adoption and are also adopted by reference. These adoptions by reference include no future editions or amendments. Copies of test methods referenced in this section are available at the Maricopa County Air Quality Department, 1001 N. Central Ave., Phoenix, Arizona 85004.

a. EPA Method 18 ("Measurement of Gaseous Organic Compound Emissions by Gas Chromatography") and its submethods (40 CFR 60, Appendix A).

b. EPA Test Method 24 ("Determination of Volatile Matter Content, Water Content, Density, Volume Solids, and Weight Solids of Surface Coatings") and its submethods (40 CFR 60, Appendix A).

c. EPA Method 25 ("Determination of Total Gaseous Nonmethane Organic Emissions as Carbon") and its submethods (40 CFR 60, Appendix A).

d. California's Bay Area Air Quality Management District (BAAQMD) Method 31 (April 15, 1992), "Determination of Volatile Organic Compounds in Paint Strippers, Solvent Cleaners, and Low Solids Coatings".

e. EPA Method 415.1 as proposed by Sorrell, et. al. of EPA's Emission Measurement Center, Office of Air Quality Planning & Standards (OAQPS): "Total Organic Carbon for Offset Lithographic Solutions," 1992.

f. ASTM Test Method D 2879-83, "Vapor Pressure-Temperature Relationship and Initial Decomposition Temperature of Liquids by Isoteniscope," 1983 edition.

503 CONDENSER TEMPERATURE: In cases where the condenser outlet gas temperature is not readily measurable due to negligible gas flow rate, the temperature of the condenser coolant may be used in lieu of condenser outlet gas temperature. In such cases, an exceedance of coolant temperature is an exceedance of the outlet gas temperature limits in Table 1, subsection 301.1 of this rule.

504 FORMULA FOR TOTAL VOC VAPOR PRESSURE: The sum of the partial pressures of the compounds defined as VOCs may be calculated by using the following formula:

$$Pp_C = \frac{\sum_{i=1}^{n} \left(W_j\right)(VP) \Big/ MW_i}{\frac{W_w}{18} + \sum_{j=1}^{m} \frac{W_{ej}}{MW_{ej}} + \sum_{i=1}^{n} \frac{W_i}{MW_i}}$$

Where:

W_i = Weight of the "i"th VOC compound in grams

W_w = Weight of water in grams

W_{ej} = Weight of the "j"th non-precursor compound in grams

MW_j = Molecular weight of the "i"th VOC compound in grams per gram mole, e.g., one gram-mole of isopropyl alcohol weighs 60 grams

MW_{ej} = Molecular weight of the "j"th non-precursor compound, e.g., 1 gram-mole of acetone weighs 58 grams

Pp_C = VOC composite partial pressure at 20°C in mm mercury (Hg)

VP = Vapor pressure of the "i"th VOC compound at 20°C in mm Hg

18 = Weight of one gram-mole of water