MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

AIR QUALITY DIVISION

PART 6. EMISSION LIMITATIONS AND PROHIBITIONS— EXISTING SOURCES OF VOLATILE ORGANIC COMPOUND EMISSIONS

R 336.1625 Emission of volatile organic compounds from existing equipment utilized: in manufacturing synthesized pharmaceutical products.

Rule 625. (1) A person shall not cause or allow the emission of any volatile organic compound from existing equipment utilized in the manufacturing of synthesized pharmaceutical products, unless all of the provisions of the following subrules are met or unless an equivalent control method, as approved by the department, is implemented.

(2) A person shall not operate an existing reactor, distillation operation, crystallizer, centrifuge, or vacuum dryer, unless the emissions from this equipment are controlled by either of the following:

(a) A condenser, such that the outlet gas temperature does not exceed the following levels:

(i) Minus 25 degrees Celsius (minus 13 degrees Fahrenheit) when the sum of the partial pressure or pressures of the volatile organic compound or compounds in the gas stream, as measured at 20 degrees Celsius (68 degrees Fahrenheit), is greater than 300 millimeters of mercury (5.8 pounds per square inch).

(ii) Minus 15 degrees Celsius (5 degrees Fahrenheit) when the sum of the partial pressure or pressures of the volatile organic compound or compounds in the gas stream, as measured at 20 degrees Celsius (68 degrees Fahrenheit), is greater than 150 millimeters of mercury (2.9 pounds per square inch).

(iii) Zero degrees Celsius (32 degrees Fahrenheit) when the sum of the partial pressure or pressures of the volatile organic compound or compounds in the gas stream, as measured at 20 degrees Celsius (68 degrees Fahrenheit), is greater than 75 millimeters of mercury (1.5 pounds per square inch).

(iv) Ten degrees Celsius (50 degrees Fahrenheit) when the sum of the partial pressure or pressures of the volatile organic compound or compounds in the gas stream, as measured at 20 degrees Celsius (68 degrees Fahrenheit), is greater than 52.5 millimeters of mercury (1.0 pounds per square inch).

(v) Twenty-five degrees Celsius (77 degrees Fahrenheit) when the sum of the partial pressure or pressures of the volatile organic compound or compounds in the gas stream, as measured at 20 degrees Celsius (68 degrees Fahrenheit), is greater than 26.2 millimeters of mercury (0.5 pounds per square inch).

(b) An alternative control technology, the use of which results in an emission level no greater than would occur by meeting the provisions of subdivision (a) of this subrule. For purposes of comparing the actual emission level from an alternative control technology to the allowable emission level resulting from meeting the provisions of subdivision (a) of this subrule, the actual emission level shall be determined using the methods described in R 336.2004 and the allowable emission level shall be determined using the calculation methods described in appendix B of "Control of Volatile Organic Emissions From Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029, December 1978. Appendix B of EPA-450/2-78-029 is adopted by

reference in these rules. A copy of the document may be obtained without charge from the Air Quality Division, Department of Environmental Quality, 106 West Allegan Street, P. O. Box 30260, Lansing, Michigan 48909-7760, or from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, Document No. PB-290580, at a cost as of the time of adoption of these rules of $41.00 each.

(3) For the purpose of this rule, the sum of the partial pressure or pressures of the volatile organic compound or compounds in the gas stream is to be determined as follows:

$$Pi = \sum_{i=1}^{n} (Pi)(Xi)$$

Where:

Pt = Sum of the partial pressures of all volatile organic compounds.

Pi = Vapor pressure of volatile organic compounds at 20 degrees Celsius (68 degrees Fahrenheit).

Xi = Mole fraction of volatile organic compounds in liquid mixture.

n = Number of different volatile organic compounds in liquid mixture.

I = Individual volatile organic compound.

The mole fraction, Xi, is determined as follows:

$$Xi = \frac{moles\ of\ \text{"i" in liquid mixture}}{total\ moles\ of\ liquid\ mixture}$$

The total moles of liquid mixture shall include both the moles of volatile organic compounds and volatile inorganic compounds (such as water) in the liquid mixture.

(4) Notwithstanding the provisions of subrule (2)(a) of this rule, a person shall not be required to reduce the temperature of a gas stream below the freezing point of a condensable component in that gas stream if it can be demonstrated, using intrinsic chemical data to the satisfaction of the department, that in doing so, the condenser would be rendered ineffective. In this case, the temperature of the gas stream shall be reduced as low as can be achieved without freezing of the condenser occurring.

(5) The provisions of this rule do not apply to any single existing reactor, distillation operation, crystallizer, centrifuge, or vacuum dryer that has a maximum uncontrolled volatile organic compound emission rate of less than 15 pounds per day.

(6) A person shall not operate an existing air dryer or production equipment exhaust system unless the volatile organic compound emissions from this equipment are reduced by not less than 90% if the uncontrolled volatile organic compound emissions are 330 pounds per day or more or are reduced to less than or equal to 33 pounds per day if the uncontrolled volatile organic compound emissions are less than 330 pounds per day.

(7) A person shall not load or allow the loading of a volatile organic compound that has a vapor pressure of more than 210 millimeters of mercury (4.1 pounds per square inch), as measured at 20 degrees Celsius (68 degrees Fahrenheit), from a truck or railcar into an existing stationary vessel of more than a 2,000-gallon capacity, unless a vapor balance system or an alternate control system that provides not less than 90% control of loading emissions is utilized.

(8) A person shall not store a volatile organic compound that has a vapor pressure of more

than 75 millimeters of mercury (1.5 pounds per square inch), as measured at 20 degrees Celsius (68 degrees Fahrenheit), in an existing aboveground stationary vessel, unless the stationary vessel is equipped with a pressure/vacuum conservation vent set at plus or minus 1.5 millimeters of mercury (0.03 pounds per square inch) or an alternate control system at least as effective. For purposes of comparing the actual emission level from an alternative control technology to the allowable emission level resulting from the use of a pressure/vacuum conservation vent meeting this requirement, the actual emission level shall be determined using the methods described in R 336.2004 and the allowable emission level shall be determined using the calculation methods described in appendix B of "Control of Volatile Organic Emissions From Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029, December 1978. Appendix B of EPA-450/2-78-029 is adopted by reference in subrule (2)(b) of this rule.

(9) A person shall not operate an existing centrifuge, rotary vacuum filter, or other filter that has an exposed liquid surface, where the liquid contains a volatile organic compound or compounds and the sum of the partial pressure or pressures of volatile organic compound or compounds is 26.2 millimeters of mercury (0.5 pounds per square inch) or more, as measured at 20 degrees Celsius (68 degrees Fahrenheit), unless the equipment is enclosed.

(10) A person shall not operate an existing in-process tank that may contain a volatile organic compound at any time, unless the tank is equipped with a cover and the cover remains closed, except when production, sampling, maintenance, or inspection procedures require operator access.

(11) A person shall not operate any existing equipment utilized in the manufacturing of synthesized pharmaceutical products from which a liquid containing a volatile organic compound or compounds can be observed dripping or running, unless the leak is repaired immediately, if possible, but not later than the first time the equipment is off-line for a period of time that is long enough to complete the repair.

(12) A person who is responsible for the operation of a synthesized pharmaceutical process subject to the provisions of this rule shall obtain current information and maintain records that are necessary for a determination of compliance with the provisions of this rule. The information shall include all of the following:

(a) For operations subject to the provisions of subrule (2) of this rule, all of the following information:

(i) A list of all volatile organic compounds in each gas stream.

(ii) The vapor pressure, as measured at 20 degrees Celsius (68 degrees Fahrenheit), of each volatile organic compound.

(iii) The mole fraction of each volatile organic compound in the liquid mixture.

(iv) Continuous records of the gas outlet temperature of each condenser or of a parameter that ensures proper operation of an equivalent control device used pursuant to subrule (2)(b) of this rule.

(b) For operations that are in compliance with the exemption provisions of subrule (5) of this rule, the amount of material entering and exiting each reactor, distillation operation, crystallizer, centrifuge, and vacuum dryer.

(c) For air dryers subject to the provisions of subrule (6) of this rule, the amount of material entering and exiting each air dryer.

(d) For operations subject to the provisions of subrule (7) of this rule, the following information:

(i) The date when each stationary vessel is loaded.

(ii) The type and vapor pressure, as measured at 20 degrees Celsius (68 degrees Fahrenheit), of each volatile organic compound loaded into each stationary vessel.

(e) For operations subject to the provisions of subrule (9) of this rule, all of the following information:

(i) A list of all volatile organic compounds in the liquid.

(ii) The vapor pressure, as measured at 20 degrees Celsius (68 degrees Fahrenheit), of each volatile organic compound.

(iii) The mole fraction of each volatile organic compound in the liquid mixture.

(f) For operations subject to the provisions of subrule (11) of this rule, the following information:

(i) The date each leak was detected.

(ii) The date each leak was repaired.

History: 1979 ACS 7, Eff. Aug. 22, 1981; 1993 MR 4, Eff. Apr. 28, 1993; 2000 MR 18 , Nov. 30 , 2000.