

Chapter 129 -- Standards for Sources

SOURCES OF VOCs

§ 129.68. Manufacture of synthesized pharmaceutical products.

(a) This section applies to synthesized pharmaceutical manufacturing facilities.

(b) The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this section shall control the VOC emissions from reactors, distillation operations, crystallizers, centrifuges and vacuum dryers that emit 15 pounds per day or more of VOC. Surface condensers or equivalent controls shall be used if:

(1) Surface condensers are used, the condenser outlet gas temperature may not exceed:

(i) -25°C when condensing VOC of vapor pressure greater than 5.8 psi (40 kilopascals) when measured at 68°F .

(ii) -15°C when condensing VOC of vapor pressure greater than 2.9 psi (20 kilopascals) when measured at 68°F .

(iii) 0°C when condensing VOC of vapor pressure greater than 1.5 psi (10 kilopascals) when measured at 68°F .

(iv) 10°C when condensing VOC of vapor pressure greater than 1 psi (7 kilopascals) when measured at 68°F .

(v) 25°C when condensing VOC of vapor pressure greater than .5 psi (3.5 kilopascals) when measured at 68°F .

(2) Equivalent controls are used, the VOC emissions shall be reduced by an equivalent or greater amount than would be required in paragraph (1).

(c) The owner or operator of a synthetic pharmaceutical manufacturing facility subject to this section shall reduce the VOC emissions from air dryers and production equipment exhaust systems:

(1) By at least 90% if emissions are 220 pounds per day (100 kilograms per day) or more of VOC.

(2) To 33 pounds per day or less if emissions are less than 220 pounds per day of VOC.

(d) The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this section shall enclose centrifuges, rotary vacuum filters and other filters having an exposed

liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of .5 psi (3.5 kilopascals) or more at 20°C.

(e) The owner or operator of a synthesized pharmaceutical facility subject to this section shall install covers on in-process tanks containing a VOC at any time. These covers shall remain closed, unless production, sampling, maintenance or inspection procedures require operator access.

(f) The owner or operator of a synthesized pharmaceutical manufacturing facility subject to this section shall repair leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off-line for a period of time long enough to complete the repair.