

**REGULATION 8
ORGANIC COMPOUNDS
RULE 24
PHARMACEUTICAL AND COSMETIC MANUFACTURING OPERATIONS**

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**REGULATION 8
ORGANIC COMPOUNDS
RULE 24**

PHARMACEUTICAL AND COSMETIC MANUFACTURING OPERATIONS

8-24-100 GENERAL

8-24-101 Description: The purpose of this Rule is to limit emissions of organic compounds from the manufacture of pharmaceutical and cosmetic products or devices.

8-24-110 Exemption, Small User: The requirements of Sections 8-24-301, 302, 303, 305, 306, 307 and 502 shall not apply to facilities that emit, 6.8 kg (15 lbs) per day or less of unabated organic compounds provided the requirements of Section 8-24-501 are met. (Calculations shall not include surface preparation and cleanup solvent.)

(Amended July 11, 1990)

8-24-111 Exemption, Ethylene Oxide Sterilizers: Ethylene oxide sterilizers which are subject to the provisions of Regulation 11, Rule 9, are exempt from the provisions of Section 8-24-303.

(Adopted July 11, 1990)

8-24-200 DEFINITIONS

8-24-201 Cosmetics Manufacturing Plant: Any plant producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetic products.

8-24-202 In-Process Tank: Containers used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals or cosmetics.

8-24-203 Organic Compound: Any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides, or carbonates, ammonium carbonates, methane, trichlorofluoromethane (CFC-11), dichlorodifluoromethane (CFC-12), chlorodifluoromethane (CFC-22), trifluoromethane (CFC-23), trichlorotrifluoroethane (CFC-113), dichlorotetrafluoroethane (CFC-114), chloropentafluoroethane (CFC-115), 1,1,1, trichloroethane and methylene chloride.

8-24-204 Pharmaceutical Manufacturing Plant: Any plant producing or blending chemicals for use in pharmaceutical products and/or employing chemical processes in the manufacture of pharmaceutical products or medical devices.

8-24-205 Approved Emission Control System: A system for reducing emissions to the atmosphere, consisting of an abatement device and a collection system, which achieves the abatement efficiency specified in the applicable standards at all times during the operation of the equipment being controlled. (Adopted June 15, 1994)

8-24-206 Key System Operating Parameter: An emission control system operating parameter, such as temperature, flow rate or pressure, that ensures operation of the abatement equipment within manufacturer specifications and compliance with the standards in Section 8-24-301.2, 302, 303, and 305. (Adopted June 15, 1994)

8-24-300 STANDARDS

8-24-301 Reactors, Distillation Columns, Crystallizers & Centrifuges: A person shall not emit more than 6.8 kg (15 lbs) or organic 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 for the control of organic compounds having the outlet gas temperature controlled as follows:

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

301.2 Any other approved emission control system that meets the requirements of Regulation 2, Rule 1 that reduces emissions by at least as much as would have occurred using a surface condenser specified in subsection 8-24-301.1

(Amended July 11, 1990; June 15, 1994)

8-24-302 Separation Operations: A person shall not emit more than 15 kg (33 lbs) or organic 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 combined 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.

(Amended July 11, 1990)

8-24-303 Sterilizers: A person shall not operate any chemical sterilizer using gaseous organic compounds unless the following condition is met:

303.1 Deleted July 11, 1990

303.2 Emissions of organic compounds shall not exceed 15 kg (33 lbs) per day from any such sterilizer unless such emissions are reduced by at least 75% on a mass basis.

(Amended July 11, 1990)

8-24-304 In-Process Tanks: A person shall not use in-process tanks for material containing organic liquids unless a cover is provided. These covers must remain closed, unless production, sampling, maintenance, loading or unloading procedures require operator access.

8-24-305 Air Dryers: A person shall not emit more than 15 kg (33 lbs) of organic compounds per day from any air dryer unless such emissions are reduced by at least 90 percent by weight.

8-24-306 Bulk Loading: A person shall not transfer organic liquids having vapor pressure 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.

8-24-307 Storage Tanks: All storage tanks that store 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 \pm 2 mm Hg (\pm 0.03 psia).

8-24-308 Operating Requirements: An operator shall repair all leaks from which organic liquids can be observed to be running or dripping. The repair shall be completed the first time the equipment is off-line for a period long enough to complete the repair.

8-24-309 Surface Preparation and Cleanup Solvent: The requirements of this Section shall apply to any person using organic solvent for surface preparation and cleanup.

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

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

(Adopted July 11, 1990)

8-24-400 ADMINISTRATIVE REQUIREMENTS

8-24-401 Deleted July 11, 1990

8-24-402 Compliance Schedule, Loss of Exemption: Any person who becomes subject to the requirements of this Rule through loss of exemption in Section 110 shall comply with the following increments of progress.

402.1 By January 1, 1991, submit an application to the APCO for Authority to Construct.

402.2 By June 1, 1991, be in final compliance. (Adopted July 11, 1990)

8-24-500 MONITORING AND RECORDS

8-24-501 Smaller-User Records: Any person seeking to satisfy the conditions of Section 8-24-110 shall comply with the following requirements:

501.1 The user shall keep records on a daily basis which show the types and amounts of organic compounds used.

501.2 Such records shall be retained and available for inspection by the APCO for the previous 24-month period. (Adopted July 11, 1990)

8-24-502 Organic Compound Processing Records: Any person subject to Sections 8-24-301, 302, 303, or 305 shall:

502.1 Maintain a current list of organic compounds in use including the vapor pressure of each compound at 20°C.

502.2 Record on a daily basis the types and amounts of organic compounds used.

502.3 Record on a daily basis approved emission control system key system operating parameters.

502.4 Retain and have such records available for inspection by the APCO for the previous 24-month period. (Adopted July 11, 1990; Amended June 15, 1994)

8-24-600 MANUAL OF PROCEDURES

8-24-601 Analysis of Samples: Samples of organic compounds as specified in Section 8-24-300 shall be analyzed as prescribed in the Manual of Procedures, Volume III, Method 13. (Adopted March 17, 1982; Amended July 11, 1990)

8-24-602 Determination of Emissions: Emissions of organic compounds as specified in Sections 8-24-110, 301, 302, 303 and 305 shall be measured as prescribed by any of the following methods: 1) BAAQMD Manual of Procedures, Volume IV, ST-7, 2) EPA Method 25 or 25A. When either EPA Method 25 or 25A is used control device equivalency shall be determined as prescribed in 55 FR 26865 (June 29, 1990). A source shall be considered in violation if the VOC emissions measured by any of the referenced test methods exceed the standards of this rule.

(Adopted March 17, 1982; Amended June 15, 1994)