

§ 439.17

PRETREATMENT STANDARDS (PSES)—
Continued

Regulated parameter	Maximum daily ¹	Maximum monthly average ¹
Methylene chloride	3.0	0.7
Chloroform	0.1	0.03
1,2-dichloroethane	20.7	8.2
Chlorobenzene	3.0	0.7
o-Dichlorobenzene	20.7	8.2
Diethyl amine	255.0	100.0
Triethyl amine	255.0	100.0

¹ mg/L (ppm)
² Not applicable to sources that discharge to a POTW with nitrification capability.

(b) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

[68 FR 12272, Mar. 13, 2003]

§ 439.17 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the same standards as specified in § 439.16.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.2(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(b) The pretreatment standards for cyanide are as follows:

Regulated parameter	Pretreatment standards ¹	
	Maximum daily discharge	Average monthly discharge must not exceed
Cyanide (T)	33.5	9.4

¹ Mg/L (ppm).

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in § 439.17(b) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the standards in paragraph (b) or (c) of this section may

be achieved by certifying to the permit issuing authority that a facility's manufacturing processes neither use nor generate cyanide.

[63 FR 50429, Sept. 21, 1998; 64 FR 10393, Mar. 4, 1999; 64 FR 48104, Sept. 2, 1999, as amended at 68 FR 34832, June 11, 2003]

Subpart B—Extraction Products

§ 439.20 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by extraction.

[63 FR 50430, Sept. 21, 1998]

§ 439.21 Special definitions.

For the purpose of this subpart:

(a) *Extraction* means process operations that derive pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

(b) *Product* means any substance manufactured by an extraction process, including blood fractions, vaccines, serums, animal bile derivatives, endocrine products and medicinal products such as alkaloids that are isolated from botanical drugs and herbs.

[68 FR 12272, Mar. 13, 2003]

§ 439.22 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD₅ is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for BOD₅ that is less than the equivalent of 45 mg/L.

(1) The long-term average daily BOD₅ load of the raw process wastewater (*i.e.*, the base number to which the percent reduction is applied) is defined as the average daily BOD₅ load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more

Environmental Protection Agency

§ 439.25

periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD₅ load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD₅ loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD₅ may be achieved by any of several, or a combination, of these practices.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) Except for the provisions in paragraph (d) of this section, the limitations for COD are as follows:

Regulated parameter	Maximum daily ¹	Maximum monthly average ¹
COD	228	86

¹ mg/L (ppm)

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then a monthly average limitation for COD corresponding

to the lower concentration value must be applied.

[63 FR 50430, Sept. 21, 1998, as amended at 68 FR 12273, Mar. 13, 2003]

§ 439.23 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT: Limitations for BOD₅, TSS and pH are the same as the corresponding limitations in § 439.22.

[63 FR 50430, Sept. 21, 1998]

§ 439.24 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: Limitations for COD are the same as the corresponding limitations in § 439.22(c) and (d).

[63 FR 50431, Sept. 21, 1998]

§ 439.25 New source performance standards (NSPS).

(a) Any new source subject to this subpart must achieve the following standards:

PERFORMANCE STANDARDS (NSPS)

Regulated parameter	Maximum daily ¹	Maximum monthly average ¹
BOD ₅	35	18
TSS	58	31
COD	228	86

¹ mg/L (ppm)

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the