

(These preparations do not include products such as lipsticks or perfumes that serve to enhance appearance, or provide a pleasing odor, but do not enhance skin care. Also excluded are deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

(c) The provisions of this part do not apply to wastewater discharges resulting from the manufacture of the following products, or as a result of providing one or more of the following services:

(1) Surgical and medical instruments and apparatus reported under SIC 3841;

(2) Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC 3842;

(3) Dental equipment and supplies reported under SIC 3843;

(4) Medical laboratory services reported under SIC 8071;

(5) Dental laboratory services reported under SIC 8072;

(6) Outpatient care facility services reported under SIC 8081;

(7) Health and allied services reported under SIC 8091, and not classified elsewhere;

(8) Diagnostic devices other than those reported under SIC 3841;

(9) Animal feed products that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(10) Food and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products;

(11) Pharmaceutical products and intermediates subject to the provisions of 40 CFR part 414, provided their manufacture results in less than 50 percent of the total flow of process wastewater that is regulated by 40 CFR part 414 at the facility.

[63 FR 50424, Sept. 21, 1998]

§ 439.1 General definitions.

As used in this part:

(a) The general definitions, abbreviations and methods of analysis in 40 CFR part 401 shall apply.

(b) The term *bench-scale operation* means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) The term *cyanide (T)* means the parameter total cyanide.

(d) The term *in-plant monitoring point* means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters enroute to the end-of-pipe.

(e) The term *minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(f) The term *nitrification capability* means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an increase in the concentrations of nitrites and nitrates.

(g) The term *non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

(h) The term *pilot-scale operation* means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(i) The term *POTW* means publicly owned treatment works (40 CFR 403.3).

(j) The term *process wastewater*, as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active anti-microbial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials

are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(k) The term *non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor “toxic” pollutants (40 CFR 401.15).

(l) The term *surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in Appendix A to this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(m) The term *xylenes* means a combination of the three isomers: o-xylene, p-xylene, and m-xylene.

(n) The abbreviation Mg/L means milligrams per liter or parts per million (ppm).

[63 FR 50425, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]

§ 439.2 Monitoring requirements.

Unless otherwise noted, self-monitoring will be conducted at the final effluent discharge point.

§ 439.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

[63 FR 50425, Sept. 21, 1998]

§ 439.4 Monitoring requirements.

Permit limits and compliance monitoring are required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, and reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and the measurement of a non-detect value for each regulated pollutant or its surrogate. Permits shall specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

[63 FR 50425, Sept. 21, 1998]

Subpart A—Fermentation Products Subcategory

§ 439.10 Applicability.

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

[63 FR 50426, Sept. 21, 1998]

§ 439.11 Specialized definitions.

For the purpose of this subpart:

(a) The term *fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.