33.6 Analytical Method for the Determination of Polyethylene Glycol 600 in Wastewater

EPA has determined that GC/MS methods have not been found to be useful in the determination of polyethylene glycol 600 in wastewater. EPA invites suggestions concerning the analysis of this pollutant in wastewater.

33.7 COD Determinations in Samples With High Chloride Content

EPA is aware that the standard method determinations of COD in samples with high chloride content (e.g., brackish wastewater) need to be pretreated to remove chloride prior to the oxidation step in the COD determination. EPA requests comments regarding the techniques used to remove chlorides prior to the oxidation step and their adequacy in preventing interference with the COD determinations. EPA also solicits data and information with respect to any analytical method studies involving COD determinations in wastewaters with high chloride concentrations.

34.0 Surface Impoundments

EPA is concerned about the transfer of volatile organic pollutants from surface impoundments located at pharmaceutical manufacturing facilities to groundwater and air. EPA solicits comment and data on the monitoring of surface impoundments, including leachate data and air emissions data.

35.0 Regulatory Impact Analysis

EPA solicits comments concerning the methodology employed to estimate costs and benefits in the Regulatory Impact Analysis developed for these regulations and the conclusions EPA reached by applying those methodologies.

36.0 Economic Impact Analysis

EPA solicits comments on the methodology employed to measure the economic impacts of the proposed regulations.

36.1 Definition of Small Entities

The Agency solicits comment on the definition of small entity used in this analysis, the analytical procedures for assessing impacts on small entities, and the opportunities to minimize the impacts on small entities, as described in the Economic Impact Analysis and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry.

37.0 Use of Bulk Parameters to Represent Pollutants of Concern

EPA solicits comments and data on the use of bulk parameters such as COD

to represent the presence and treatability of pollutants of concern, such as the broad range of organic compounds present in pharmaceutical manufacturing process wastewaters, particularly chemical synthesis process wastewaters. See also solicitation numbers 10.0, 20.0, 26.0, 27.0, and 28.0.

38.0 Reducing Monitoring Requirements

The Agency solicits comment on ways to reduce the monitoring requirements associated with the proposed rulemaking.

38.1 Subcategory D Facilities

The Agency is aware that many facilities with subcategory D operations do not use or generate the pollutants for which regulations are being proposed today. Consequently, these facilities should not be required to monitor for these pollutants. EPA solicits comment on any appropriate mechanism for reducing monitoring requirements for these facilities.

38.2 Pollutants Not Used or Generated

Similarly, facilities with operations in other subcategories may not use or generate specific pollutants for which regulations are being proposed. EPA solicits comment on any appropriate mechanism for reducing monitoring requirements for these pollutants at such facilities.

38.3 Use of Alternate Analytical Methods

EPA also solicits comments on whether circumstances may exist under which it may be appropriate to allow facilities to use analytical methods for organic pollutants other than those used to generate data upon which this proposal is based. Such circumstances may include "screening" to confirm the absence of pollutants where solvents are not used in pharmaceutical manufacturing processes (i.e., subcategory D, mixing/compounding/formulating). These alternate methods might include Methods 624 and 625 as alternatives to Methods 1624 and 1625.

39.0 Privately Owned Treatment Plants

EPA solicits comment on the issue whether part 439 should apply to process wastewater pollutants introduced into privately owned treatment works.

List of Subjects in 40 CFR Part 439

Environmental Protection Air pollution control, pharmaceutical manufacturing Pollution prevention, Wastewater treatment. Dated: February 28, 1995.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 439 of the Code of Federal Regulations is proposed to be amended as follows:

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for part 439 is revised to read as follows:

Authority: Sections 301, 304, 306, 307, and 501 of the Clean Water Act, (33 U.S.C. 1311, 1314, 1316, 1317, and 1361).

2. The Table of Contents for part 439 is amended by adding §§ 439.3 and 439.4 and the entire table of contents is published for the convenience of the reader.

Sec.

439.0 Applicability.

439.1 General definitions.

439.2 Monitoring requirements.

439.3 Dilution prohibition.

439.4 [Reserved]

Subpart A—Fermentation Subcategory

439.10 Applicability; description of the fermentation products subcategory.

439.11 Specialized definitions.

- 439.12 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (RPT).
- 439.13 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
- 439.14 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).
- 439.15 New source performance standards (NSPS).
- 439.16 Pretreatment standards for existing sources (PSES).
- 439.17 Pretreatment standards for new sources (PSNS).

439.18 [Reserved]

Subpart B—Extraction Subcategory

439.20 Applicability; description of the extraction products subcategory.

439.21 Specialized definitions.

- 439.22 Effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available (BPT).
- 439.23 Effluent limitations representing the degree of effluent reduction attainable by the best conventional pollutant control technology (BCT).
- 439.24 Effluent limitations representing the degree of effluent reduction attainable by the application of best available technology economically achievable (BAT).