



November 20, 2018

Amgen
40 Technology Way
West Greenwich, RI 02817
401.392.1200
www.Amgen.com

Ms. Karen Slattery
Rhode Island Department of Environmental Management
Office of Air Resources
235 Promenade Street
Providence, Rhode Island 02908

RE: Comments on draft regulation 250-RICR-120-05-36 – Control of Emissions from Organic Solvent Cleaning

Dear Ms. Slattery:

Immunex Rhode Island Corporation, a subsidiary of Amgen (Immunex) is submitting comments on the draft regulation 250-RICR-120-05-36 Control of Emissions from Organic Solvent Cleaning filed on 10/30/2018. Immunex appreciates your consideration in reviewing of these comments.

Immunex is proposing two additional exemptions to section 36.6.D as shown in the RIDEM issued proposed regulation:

Proposed Exemption	Rational
Update 36.6.D.6 – Clarify that Pharmaceutical Manufacturing also includes Biological Product Manufacturing	Biological Product Manufacturing operations are similar to pharmaceutical; however the NAICS codes are different. This change will allow Biological Product Manufacturers (NAICS code: 325414) to be included in the exempted pharmaceutical category (NAICS code: 325412)
Add a new exemption 36.6.D.17 – Organic solvent emissions which are permitted through Air Pollution Control regulations Part 9 – Air Pollution Control Permits (250-RICR-120-05-9)	Permitted emissions have already gone through the rigorous requirements to minimize and control emissions by completing a RACT/BACT analysis and permitted emissions sources have demonstrated that fence-line emissions will not exceed the Acceptable Ambient Levels listed in Air Pollution Control regulation Part 22 – Air Toxics. For example, Immunex has an existing permit which included a BACT analysis for these types of emissions.

Immunex has included below draft wording for Section 36.6.D for your consideration. Note, the numerals and letters are updated to reflect the issued red-lines. For example, 36.6.B in the red-line should be 36.6.C.

36.6 Applicability

A. The owner or operator of an organic solvent cleaning machine as defined in § 36.5(A)(35) of this Part, shall comply with the requirements of § § 36.7 through 36.15 of this Part, as applicable.

B. Whereever the term “Volatile Organic Compound” or “VOC” appears in § 36.5 through §36.17 of this Part, read this to mean “Volatile Organic Compounds and Halogenated Organic Compounds” or “VOC” and “HOC.”

C. The requirements in §36.9 of this Part shall not apply to any cold solvent cleaning machine that uses a solvent which contains no more than five percent (5%) VOC or volatile HAP by weight.

D. The requirements of this regulation, with the exception of §36.13(E) and (F) of this Part, shall not apply to any cold solvent cleaning machine that has an internal volume of one (1) liter or less.

E. The owner or operator of a facility at which cleaning solvents are used for industrial solvent cleaning as defined in § 36.5(A)(22) of this Part, which has actual VOC emissions, before controls, greater than 2.7 tons during any consecutive 12-month period from industrial solvent cleaning activities, shall comply with the requirements of § 36.16 of this Part unless exempt as specified in §§ 36.6(D)(1) through (16) of this Part.

*6. Pharmaceutical **or Biological Product** Manufacturing*

*17. Organic solvent emissions permitted through Air Pollution Control regulations Part 9
– Air Pollution Control Permits (250-RICR-120-05-9)*

If you have any questions, please contact Michelle Anforth at (401) 392-1711 or at manforth@amgen.com.

Sincerely,



Rich Girasole
Senior Manager, EHSS
Immunex Rhode Island Corporation