

ENGINEERING EVALUATION
Acclarent Inc
Application #22541
Plant #19870

I. BACKGROUND

Acclarent Inc has applied for an Authority to Construct and/or Permit to Operate for the following equipment at 1525B O'Brien Drive, Menlo Park, CA 94025.

S-1 Wipe Cleaning Operation

S-1 was previously permitted in Application #21031, and the applicant is requesting a **modification** to S-1 to increase the permitted annual use of the solvents.

Acclarent Inc is a facility that designs and manufactures products for medical device and life science companies. Acclarent assembles and packages medical devices (small tools) used in sinus surgery. The facility uses the wipe cleaning operation to clean their work surfaces daily, such as bench tops. The facility also uses the wipe cleaning operation to clean the medical devices before packaging. Monthly, walls and ceilings in the assembly area are wiped with IPA (isopropyl alcohol).

Acclarent Inc currently utilizes approximately 10 gallons of 70% IPA (isopropyl alcohol) and 2 gallons 99% IPA (isopropyl alcohol) per month, which is in compliance with the current conditions. The applicant requests annual usage of 250 gallons of 70% IPA and 75 gallons 99% IPA to allow for future business growth.

II. EMISSION CALCULATIONS

Basis:

- Annual Usage: 250 gallons of 70% IPA (isopropyl alcohol), 75 gallons of 99% IPA (isopropyl alcohol)
- Operating Schedule: 10 hours/day, 5 days/week, 52 weeks/year. Assume 250 working days per year.
- Any organic solvents used at S-1 are 100% volatile and emitted into the atmosphere.

Annual Average Emissions:

Annual emissions are calculated based on the above basis for operating schedule. See Table 1.

Daily Emissions:

Daily emissions are calculated to establish whether a source triggers the requirement for BACT (10 lb/highest day total source emissions for any class of pollutants). See Table 1.

Table 1

Modified Emissions	Net Usage (gal/yr)	Density (lb/gal)	Hourly Emissions (lb/hr)	Daily Emissions (lb/day)	Annual Emissions	
					(lb/yr)	(TPY)
70% IPA (POC)*	250	6.55	0.4585	4.585	1146.25	0.573
99% IPA (POC)*	75	6.55	0.1965	1.965	491.25	0.246
Total	325	N/A	0.655	6.55	1637.5	0.819
Previous Emissions Application #21031						
70% IPA (POC)*	42.1	6.55	0.106	1.06	275.9	0.1380
99% IPA (POC)*	35.9	6.55	0.090	0.90	235.1	0.1175

* POC = Precursor Organic Compound

III. PLANT CUMULATIVE INCREASE SINCE 4/5/1991

Table 2 summarizes the cumulative increase in criteria pollutant emissions that will result at Plant 19870 from the operation/modification of S-1.

Table 2

Pollutants	Current Emissions (TPY)	Emission Increase from this application (TPY)	New Total Emissions (TPY)
POC	0.256	0.563	0.819
NO _x	0.0	0.0	0.0
SO ₂	0.0	0.0	0.0
CO	0.0	0.0	0.0
PM ₁₀	0.0	0.0	0.0
NPOC	0.0	0.0	0.0

IV. OFFSETS

Offsets must be provided for any new or modified source at a facility that emits more than 10 tons/yr of POC or NO_x per Regulation 2-2-302. According to Table 2 that summarizes the increase in criteria pollutant emissions that will result from the operation of S-1, offsets are not required because the facility will emit less than 10 tons per year of POC.

V. TOXIC SCREENING ANALYSIS

Table 3

Toxic Pollutant Emitted	Hourly Emission Rate (lb/hr)	Acute Trigger for Risk Screen (lb/hr)	Acute Triggered?	Annual Emission Rate (lb/yr)	Chronic Trigger for Risk Screen (lb/yr)	Chronic Triggered?
IPA	0.655	7.1	No	1637.5	270,000	No

As shown in Table 3, emissions of toxic air contaminants from S-1 do not exceed any District trigger level of Regulation 2-5, and a Toxics Risk Screen is therefore not required.

VI. BEST AVAILABLE CONTROL TECHNOLOGY (BACT)

In accordance with Regulation 2, Rule 2, Section 301, BACT is triggered for any new or modified source with the potential to emit 10 pounds or more per highest day of POC, NPOC, NO_x, CO, SO₂ or PM₁₀. With the highest daily POC emissions not in excess of 10 pounds, S-1 Wipe Cleaning Operation does not trigger the BACT requirements Regulation 2-2-301.1.

VII. STATEMENT OF COMPLIANCE

Wipe cleaning operation S-1 is subject to and expected to comply with the storage and disposal requirements of Regulation 8-1-320 (*Surface Preparation; Clean-up; Coating, Ink, Paint Removal*), 321 (*Closed Containers*), and 322 (*Spray Equipment Clean-up Limitation*) and the recordkeeping requirements of Regulation 8-16-501 (*Solvent Records*) and Regulation 8-4-501 (*Recordkeeping Requirements*).

Per Regulation 8-4-116 (*Limited Exemption, Specific Surface Preparation and Cleaning Operations*), S-1 is exempt from Regulation 8-4-313 (*Surface Preparation Standards*), because S-1 is used for surface preparation associated with medical device manufacturing operations.

S-1 is subject to and expected to comply with the 5 TPY VOC limit per Regulation 8-4-302.1 (*Solvents and Surface Coating Requirements*) since the permit condition will limit S-1 to 1637.5 lbs of POC.

The proposed project is considered to be ministerial under Regulation 2-1-311 (*Ministerial Projects*) and therefore is not subject to California Environmental Quality Act (CEQA) review. The engineering review for this project requires no more than the application of standard permit conditions and standard emission factors as described in the District's Permit Handbook Chapter 6.3 and therefore is not considered discretionary as defined by CEQA.

A Toxics Risk Screening Analysis is not required due to the emissions of IPA at the rates discussed above. TBACT does not apply to this project.

Pursuant to Regulation 2-2-304 (*PSD Requirement*), this project is not subject to PSD review because the facility is not a major facility emitting more than 100 TPY.

Offsets, NSPS, and NESHAPS are not triggered.

This facility is less than 1,000 feet from the nearest school and therefore is subject to the public notification requirements of Regulation 2-1-412 (*Public Notice, Schools*). A public notice will be prepared and sent to all addresses within 1000 feet of the modified source and parents and guardians of students of the following schools:

Costano Elementary School/ San Francisco 49ers Academy
2695 Fordham Street
East Palo Alto, CA 94303-1207

Cesar Chavez Elementary School
2450 Ralmar Avenue
East Palo Alto, CA 94303-1040

Green Oaks Elementary School
2450 Ralmar Avenue
East Palo Alto, CA 94303-1040

The public comment period lasted from XXX to XXX. At the end of the comment period, XXX.

VIII. CONDITIONS

Condition # 24484

Acclarent Inc
S-1 Wipe Cleaning Operation
Application 22541
(Amend in October 2010)
(Created March 2010 for Application 21648)

1. The owner/operator of S-1 shall not exceed the following usage limits during any consecutive twelve-month period:

70% Isopropyl alcohol	250 Gallons
99% Isopropyl alcohol	75 Gallons

 (Basis: Cumulative Increase)

2. The owner/operator may use an alternate solvent(s) other than the materials specified in Part 1 and/or usages in excess of those specified in Part 1, provided that the owner/operator can demonstrate that all of the following are satisfied:
 - a. Total POC emissions from S-1 do not exceed 1637.5 pounds in any consecutive twelve month period;
 - b. The use of these materials does not increase toxic emissions above any risk screening trigger level of Table 2-5-1 in Regulation 2-5.
(Basis: Cumulative Increase; Toxics)

3. To determine compliance with the above parts, the owner/operator shall maintain the following records and provide all of the data necessary to evaluate compliance with the above parts, including the following information:
 - a. Quantities of each type of solvent used at this source on a monthly basis.
 - b. If a material other than those specified in Part 1 is used, POC/NPOC and toxic component contents of each material used; and mass emission calculations to demonstrate compliance with Part 2, on a monthly basis;
 - c. Monthly usage and/or emission calculations shall be totaled for each consecutive twelve-month period.

All records shall be retained on-site for two years, from the date of entry, and made available for inspection by District staff upon request. These recordkeeping requirements shall not replace the recordkeeping requirements contained in any applicable District Regulations.
(Basis: Cumulative Increase; Toxics)

End of Conditions

IX. RECOMMENDATION

Issue Accelerant Inc a Change of Condition for the following equipment:

S-1 Wipe Cleaning Operation

Yu Zhang Liu
Air Quality Engineer Intern