

**ENGINEERING EVALUATION**  
**Novartis Vaccines and Diagnostics, Inc.**  
**PLANT NO. 8025**  
**APPLICATION NO. 24797**

**BACKGROUND**

Novartis Vaccines and Diagnostics, Inc. (Novartis) is applying for a Permit to Operate the following operation:

**S-57 Solvent Cleaning/Surface Preparation Bldg 4 – West**

S-57 is located at 4560 Horton Street in Emeryville, CA.

At S-57, Novartis performs solvent cleaning and surface preparation onsite for the purposes of disinfecting and removing chemical residues from work surfaces such as bench tops, medical devices, and pharmaceutical manufacturing instruments. Novartis cleans and prepares the surfaces by spraying the surfaces directly with solvents that are then evaporated to dryness and/or by wetting with solvents a wipe that is then used to rub the surfaces. The solvents used at S-57 are 70% Ethanol (and 30% water) solution and/or 70% IPA (and 30% water) solution.

The only criteria pollutant emitted from the operation of S-57 is precursor organic compounds (POC). This pollutant is briefly discussed on the District’s web site at [www.baaqmd.gov](http://www.baaqmd.gov).

This evaluation report will estimate the increase in POC emissions associated with the operation of S-57 at Novartis and will discuss the compliance of the operation with applicable District’s rules and regulations.

**EMISSIONS SUMMARY**

Novartis has proposed for use at S-57 350 gallons/year of 70% Ethanol solution and/or 70% IPA solution. The ethanol solution contains 70% POC and has a density of 6.59 lb/gal. The IPA solution contains 70% POC and has a density of 7.01 lb/gal.

For a conservative estimate of emissions, the POC emissions from the operation of S-57 will be estimated using the higher density (7.01 lb/gal) of the two solvents.

Any organic solvents used will be assumed 100% volatile and emitted into the atmosphere.

Table 1. POC emissions from operation of S-57

Solvent	Net Usage (gal/yr)	Density (lb/gal)	Hourly Emissions (lb/hr)	Daily Emissions (lb/day)	Annual Emissions	
					(lb/yr)	(TPY)
70% Ethanol and/or 70% IPA	350	7.01	0.197	4.72	1,718	0.859

Note: Operating schedule is 24 hr/day, 7 day/week, 52 week/yr.

**PLANT CUMMULATIVE INCREASE**

Novartis at “4560 Horton Street, Emeryville, CA 94608” (Plant No. 8025) was previously Cetus Corporation (Plant No. 1983). Cumulative increases post 4/5/1991 in tons/year for both plants are shown below.

Table 2. Cumulative increases post 4/5/1991 in tons/year

Pollutants	Current Increases (TPY)		New Increases (TPY)	Total Increases (TPY)
	Plant #1983	Plant #8025		
POC	0.000	0.340	0.859	1.199
NOx	0.000	2.815	0.000	2.815
SO <sub>2</sub>	0.000	0.066	0.000	0.066
CO	0.000	3.568	0.000	3.568
PM <sub>10</sub>	0.000	0.436	0.000	0.436
NPOC	0.000	0.000	0.000	0.000

**TOXIC RISK SCREENING**

Novartis may use at most 350 gallons of solvent solution at S-57 annually. The solvent cleaning solution used is either 70% Ethanol or 70% IPA. Ethanol does not appear on the District TAC (Toxic Air Contaminant) List of Table 2-5-1. IPA is listed on the list. Table 3 shows that toxic emission rates from operation of S-57 are substantially below the TAC trigger levels listed in Table 2-5-1 of Regulation 2-5. Hence, the requirements of a Health Risk Screening Analysis are not triggered.

Table 3. Toxic Air Contaminant (TAC) emissions and trigger levels

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	2.0E-01	7.1E+00	No	1.7E+03	2.7E+05	No

**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, NOx, CO, SO<sub>2</sub> or PM<sub>10</sub>. Based on the emission calculations above, the highest daily emissions of POC are not in excess of 10 pounds. Therefore, the operation of S-57 does not trigger the BACT requirements of Regulation 2-2-301.1.

**OFFSETS**

Offsets must be provided for any new or modified source at a facility that emits more than 10 tons/year of POC or NOx per Regulation 2, Rule 2, Section 302. The District may provide offsets from the Small Facility Banking Account for a facility with emissions between 10 and 35 tons/year of POC or NOx, provided that facility has no available offsets.

Cumulative increases (pre and post 4/5/1991) in tons/year for both plants are shown in Table 4. Table 4 shows POC offsets are not required because the facility will emit less than 10 tons per year of POC. NOx offsets are not required for this application because, although permitted increases of NOx total to 13.035 tons/year (in between 10 and 35 tons/year), the operation of S-57 does not result in any NOx emission increase.

Table 4. Cumulative increases in tons/year

Pollutants	Pre 4/5/91 Permitted Increases (TPY)		Post 4/5/91 Permitted Increases (TPY)		New Increases (TPY)	Total Increases (TPY)
	Plant 1983	Plant 8025	Plant 1983	Plant 8025		
POC	0.473	0.000	0.000	1.730	0.859	3.062
NO <sub>x</sub>	10.220	0.000	0.000	2.815	0.000	13.035
SO <sub>2</sub>	0.055	0.000	0.000	0.066	0.000	0.121
CO	2.372	0.000	0.000	3.568	0.000	5.940
PM <sub>10</sub>	0.000	0.000	0.000	0.436	0.000	0.436
NPOC	0.000	0.000	0.000	0.000	0.000	0.000

**STATEMENT OF COMPLIANCE**

The owner/operator of S-57 Solvent Cleaning/Surface Preparation Bldg 4 – West is exempt from Regulation 8, Rule 16 (*Organic Compounds, Solvent Cleaning Operations*) per Regulation 8-16-111 (*Exemption, Wipe Cleaning*). The owner/operator is subject to Regulation 8, Rule 4 (*Organic Compounds, General Solvent and Surface Coating Operations*).

The owner/operator of S-57 is subject to and expected to comply with the storage and disposal requirements of Regulations 8-1-320, 321, and 322. The owner/operator of S-57 is also subject to and expected to comply with the recordkeeping requirements of Regulation 8-4-501.

Per Regulation 8-4-116, The owner/operator of S-57 is exempt from the surface preparation standards of Regulation 8-4-313 because Novartis utilizes S-57 for surface preparation associated with medical device or pharmaceutical manufacturing operations. The owner/operator of S-57 is subject to and expected to comply with the 5 TPY of VOC limit of Regulation 8-4-302.1 since the permit condition will limit S-57 to 1,718 lbs per year (or 0.859 TPY) of POC. Novartis is subject to and has agreed to comply with the evaporative loss minimization requirements of Regulation 8-4-312.

The project is considered to be ministerial under the District's CEQA regulation 2-1-311 and therefore is not subject to CEQA review. The engineering review for this project requires only the application of standard permit conditions and standard emissions factors and therefore is not discretionary as defined by CEQA. (Permit Handbook Chapter 6.3)

PSD, NSPS, and NESHAPS do not apply.

The project is within 1,000 feet of Pacific Rim School (located at 5521 Doyle Street, Emeryville, CA 94608) and Emery Secondary School (located at 4727 San Pablo Avenue, Emeryville, CA 94608), and is therefore subject to the public notification requirements of Regulation 2-1-412. A public notice will be prepared and sent to:

- All addresses within 1,000 feet of the solvent cleaning/surface preparation station; and
- Parents and guardians of students at Pacific Rim School and Emery Secondary School.

All comments received will be summarized in this evaluation report.

**PERMIT CONDITIONS**

Condition #25370 -----

S-57 Solvent Cleaning/Surface Preparation Bldg 4 – West  
Plant #8025  
Application #24797 (October 2012)

1. The owner/operator of S-57 shall not use more than 350 gallons of cleaning solution containing 70% solvent (isopropyl alcohol and/or ethanol) in any consecutive 12-month period.  
(Basis: Cumulative Increase)
  
2. The owner/operator may use an alternate solvent(s) other than the material specified in Part 1 and/or usage in excess of that specified in Part 1, provided that the owner/operator can demonstrate that all of the following are satisfied:
  - a. Total POC emissions from S-57 do not exceed 1,718 pounds in any consecutive 12-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, but not necessarily limited to, the following information:
  - a. Records on a monthly basis of the type, amount, and POC content of each cleanup solvent used.
  - b. If a material other than that specified in Part 1 is used or the material specified in Part 1 is used in excess of the limit in Part 1, POC 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 12-month period.

The owner/operator shall record all records in a District-approved log. The owner/operator shall retain all records on-site for two years, from the date of entry, and make them 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; Regulation 8-4-501)

*End of Conditions*

**RECOMMENDATION**

The District has reviewed the material contained in the permit application for the proposed project and has made a preliminary determination that the project is expected to comply with all applicable requirements of District, state, and federal air quality-related regulations. The preliminary recommendation is to issue an Authority to Construct for the equipment listed below. However, the proposed source will be located within 1,000 feet of a school, which triggers the public notification requirements of District Regulation 2-1-412.6. After the comments are received and reviewed, the District will make a final determination on the permit.

I recommend that the District initiate a public notice and consider any comments received prior to taking any final action on issuance of an Authority to Construct for the following source:

**S-57 Solvent Cleaning/Surface Preparation Bldg 4 – West**

By: \_\_\_\_\_

Kevin Oei  
Air Quality Engineer

Date: \_\_\_\_\_