

ENGINEERING EVALUATION
Plant 12071: Bayer HealthCare LLC.
800 Dwight Way, Berkeley, CA, 94710

Application 27619: Modification of Facility-wide Wipe Cleaning Operation (S-13)

BACKGROUND

Bayer HealthCare LLC (Bayer) has applied for a modification to the Permit to Operate the following source at its facility (BAAQMD Plant # 12071) in Berkeley, CA:

S-13 Facility-Wide Wipe Cleaning Operation

Bayer develops and manufactures pharmaceutical products. Bayer uses isopropyl alcohol (IPA) in S-13 to clean and disinfect surfaces, in accordance with FDA Good Manufacturing Practices. The wipe cleaning operation is conducted in 13 buildings spread across the facility. The facility has proposed to increase its use of cleaning solution from 7,146 gal/year to 10,888 gal/year¹.

EMISSIONS SUMMARY

Annual Emissions:

Bayer uses a cleaning solution with 70% by weight isopropyl alcohol (IPA) and 30% by weight water in S-13. The density of the cleaning solution is 7.11 lb/gal. Assuming 100% of the solvent in the solution is emitted into the atmosphere,

$$\text{Total POC emissions from S-13} = (10888 \text{ gal/yr}) * (0.70 \text{ solvent}) * (7.11 \text{ lb/gal}) = 54190 \text{ lb/yr} = 27.095 \text{ tpy}$$

$$\text{Increase in POC emissions} = (10888 - 7146 \text{ gal/yr}) * (0.70 \text{ solvent}) * (7.11 \text{ lb/gal}) = 18624 \text{ lb/yr} = 9.312 \text{ tpy}$$

Maximum Daily Emissions:

Bayer operates 24 hrs/day, 7 days/wk, and 52 wks/yr.

$$\text{S-13 Daily Maximum POC Emission} = (54190 \text{ lb/yr}) / (365 \text{ days/yr}) = 148.5 \text{ lb/day}$$

Maximum Hourly Emissions

The maximum hourly POC emissions from S-13 are currently limited by Permit Condition 16577, Part 3 to 68.12 lb/hr. These emissions are spread across 13 buildings that constitute S-13. Bayer is neither proposing to increase/reallocate the maximum hourly POC emissions from the currently permitted levels at each building nor proposing to relocate the emission points.

Isopropyl alcohol is a precursor organic compound (POC) and a toxic air contaminant (TAC). It is not a hazardous air pollutant (HAP) as defined by Section 112(b) of the Clean Air Act.

PLANT CUMULATIVE INCREASE

Table 1 Cumulative Increase

Pollutant	Permitted Emissions (since April 5, 1991)	Emissions with This Application	Cumulative Emissions Increase
	(TPY)	(TPY)	(TPY)
NOx	11.947	0	11.947
POC	21.859	9.312	31.171
CO	12.418	0	12.418
PM10	2.229	0	2.229
SO2	0.200	0	0.200

¹ This equates to an increase in IPA usage from 5,429 gals/year to 8,272 gal per year at 6.55 lb/gal IPA density.

TOXIC RISK SCREENING ANALYSIS

The chronic trigger for IPA in BAAQMD Regulation 2-5, Table 2-5-1 is 270,000 lb/yr. At 54,190 lb/year of IPA, the total annual emissions are below the chronic trigger level.

An HRSA was conducted for the hourly permitted emissions in Permit Condition 16577, Part 3 as part of Application 18921. The HRSA assumed that the disinfection would take place at the same time in all 13 buildings for a total of 68.12 pounds of IPA/hr. The results of the HRSA showed that the above emission levels would result in a maximum project acute hazard index of 1.0 at point of maximum impact (PMI). In accordance with the BAAQMD Regulation 2-5-302, S-13 was determined to be in compliance with the project risk requirements because the acute hazard index did not exceed 1.0.

Because the maximum hourly emissions will not increase from the levels analyzed under Application 18921, annual emissions will remain below the chronic trigger levels, and other risk screen parameters, such as emission point locations and acute reference exposure level of IPA, have not changed since the last HRSA conducted for Application 18921, an HRSA is not required for this application.

BACT

Per Regulation 2-2-301, Best Available Control Technology (BACT) is required when a new or modified source has a potential to emit 10.0 pounds or more per highest day. BACT is a source and pollutant specific requirement.

S-13 will emit an average of 148.5 lb POC/day. Therefore, S-13 requires BACT.

The District’s BACT/TBACT Workbook lists the following options for BACT for wipe cleaning in Section 6, Document 179B.1.

BACT-1 (Technologically feasible) is:

Wipe cleaning in a hood, booth, or room vented to a control device, w/ emissions controlled to overall capture/destruction efficiency >90%

BACT-1 is not only technologically infeasible but also not cost-effective. So BACT-1 will not be imposed and S-13 will be required to meet BACT-2.

BACT 2 (Achieved in practice) is:

Minimizing use of solvents; and use of lowest practical vapor pressure solvents; and use of controlled flow solvent dispenser (e.g., squeeze bottle); and all cloths/papers and solvents not in active use kept in closed containers.

In this case, the District has determined that the source will comply with BACT-2 because the source has minimized the use of solvents, will use closed containers for storage, and is using the lowest practical vapor pressure solvent.

OFFSETS

Regulation 2-2-302 requires offsets for NOx and POC emission increases from any new or modified source if the facility-wide emissions of that pollutant are greater than 10 tons/year. Table 2 summarizes the increase in criteria pollutant emissions and offset requirement due to modification of S-13 at Plant 12071.

Table 2: Cumulative Emissions and Offset Requirement

Pollutant	Actual Facility Emissions per Most Recent District Inventory (TPY)	Total Permitted Emissions (Pre- + Post – 4/5/1991) (TPY)	Emissions Increase with This Application (TPY)	Adjusted Total Facility Emissions (TPY)	Regulation 2-2-302 and 2-2-303 Offset Triggers (TPY)
POC	18.374	21.859	9.312	31.171	> 10

Only POC emissions will increase due to the proposed modification of POC. Because the adjusted total facility-wide emissions exceed 10 tpy POC, any POC emissions increases from S-13 must be offset. Because the facility-wide emissions for POC are below 35 tpy and Bayer does not own emissions reduction credits (ERC), the emissions increase of POC from S-13 will be offset by the District’s Small Facility Bank.

STATEMENT OF COMPLIANCE

Solvent cleaning at S-13 requires the wiping down of manufacturing and laboratory surfaces. S-13 is exempt from all requirements in Regulation 8, Rule 16: Organic Compounds: Solvent Cleaning Operations per Regulation 8-16-111: Exemption, Wipe Cleaning, except for the recordkeeping requirements in Regulation 8-16-501.3. S-13 will comply with the recordkeeping provisions in Section 8-16-501.3, which will be incorporated in the permit conditions.

Bayer is a medical device and pharmaceutical manufacturer per Regulation 8-4-225 and is exempt from Regulation 8-4-313 per Regulation 8-4-116 Limited Exemption, Specific Surface Preparation and Cleaning Operations. In fact, S-13 is not subject to any requirements in Regulation 8, Rule 4: Organic Compounds, General Solvent and Surface Coating Operations because it is subject to Regulation 8, Rule 24, Pharmaceutical and Cosmetic Manufacturing Operations.

S-13 is subject to BAAQMD Regulation 8, Rule 24, Pharmaceutical and Cosmetic Manufacturing Operations because it is “employs chemical processes in the manufacture of pharmaceutical products.” The facility will comply with the Surface Preparation and Cleanup Solvent standards in Section 8-24-309.

This application is considered to be ministerial under the District's 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 emission factors in accordance with Permit Handbook Chapter 6.3 and therefore, is not discretionary as defined by CEQA.

PSD is not triggered because the facility is not a major facility. There are no applicable NSPS or NESHAPS.

One of the buildings in which the wipe cleaning operation will be conducted is located less than 1,000 feet from the nearest K-12 school and is therefore, subject to the public notification requirements of Regulation 2-1-412.

Bayer has also submitted another application (#27444) for two new emergency diesel engine-generators. A public notification requirement of Regulation 2-1-412 is also triggered for Application 27444. Therefore, one public notice will be prepared for both applications (27444 and 27619). A public notice will be prepared and sent to all addresses within 1,000 feet of S-13 and to the parents and guardians of students of the following school(s):

Ecole Bilingue de Berkeley Middle School
901 Grayson Street, Berkeley, CA, 94710

Global Montessori International School
2830 9th Street, Berkeley, CA, 94710

All comments received shall be summarized in final evaluation report.

PERMIT CONDITIONS

COND# 16577 -----

CONDITIONS**S13, Wipe Cleaning Operation**

1. The total emissions of isopropyl alcohol and ethanol from the S13 Wipe Cleaning Operation shall not exceed ~~17.783~~ 27.1 tons in any consecutive 12-month period. [Basis: Cumulative Increase, Regulation 2, Rule 5]
- ~~2. The owner/operator shall not use isopropyl alcohol or solutions of isopropyl alcohol at any location within the facility that is within 1,000 feet of a K-12 school. [Basis: 2-1-412]~~

3. The owner/operator shall use isopropyl alcohol or solutions of isopropyl alcohol only at Buildings 5A, 28A, 49, 49A, 50, 53, 55, 57/57A, 59, 60, 66, 80, and 81. The owner/operator shall apply to BAAQMD for a change of conditions including a health risk screening analysis to use isopropyl alcohol or solutions of isopropyl alcohol at another building in Site B2071. Hourly emissions, associated with the net usage of isopropyl alcohol, are limited at the above buildings to not exceed the following emission rates:
 - a. Building 5A: 1.52 lb/hr
(corresponds to net IPA usage of 39 fl. oz.)
 - b. Building 28A: 1.71 lb/hr
(corresponds to net IPA usage of 44 fl. oz.)
 - c. Building 49: 2.53 lb/hr lb/hr
(corresponds to net IPA usage of 65 fl. oz.)
 - d. Building 49A: 1.51 lb/hr
(corresponds to net IPA usage of 39 fl. oz.)
 - e. Building 50: 2.60 lb/hr
(corresponds to net IPA usage of 67 fl. oz.)
 - f. Building 53: 4.32 lb/hr
(corresponds to net IPA usage of 111 fl. oz.)
 - g. Building 55: 5.59 lb/hr
(corresponds to net IPA usage of 144 fl. oz.)
 - h. Building 57/57A: 1.30 lb/hr
(corresponds to net IPA usage of 33 fl. oz.)
 - i. Building 59: 0.008 lb/hr
(corresponds to net IPA usage of 0.20 fl. oz.)
 - j. Building 60: 8.17 lb/hr
(corresponds to net IPA usage of 210 fl. oz.)
 - k. Building 66: 5.27 lb/hr
(corresponds to net IPA usage of 135 fl. oz.)
 - l. Building 80: 0.86 lb/hr
(corresponds to net IPA usage of 22 fl. oz.)
 - m. Building 81: 32.73 lb/hr
(corresponds to net IPA usage of 842 fl. oz.)[Basis: Regulation 2, Rule 5]
4. Materials other than those specified in part 1 may be used at S13, provided that the owner/operator can demonstrate that all of the following requirements are satisfied:
 - a. Total precursor organic compound (POC) emissions from S13 do not exceed ~~17.783~~ 27.1 tons in any consecutive 12-month period.
 - b. No non-precursors organic compounds (NPOC) as defined by BAAQMD Regulation 1-234 are used.
 - c. No toxic air contaminant other than isopropyl alcohol is used.[Basis: Cumulative Increase, Regulation 2, Rule 5]
5. The owner/operator shall comply with the surface preparation and cleanup solvent provisions in BAAQMD Regulation 8-24-309. [Basis: Regulation 8-24-309, BACT]

6. The owner/operator shall maintain ~~monthly~~ dated facility-wide records in a District-approved log of the type and amount of solvent used in each hour. The owner/operator shall combine the hourly solvent usage records on a daily, monthly and rolling consecutive 12-month period basis. These records shall be retained for a period of at least 2 years from date of entry. The logs shall be kept on site and made available to District staff upon request.

[Basis: Cumulative Increase, Regulation 8-16-501.3]

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 a Permit to Operate with Change of Conditions for the equipment listed below. However, the proposed sources will be located within 1,000 feet of at least one school, which triggers the public notification requirements of Regulation 2-1-412. 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 a Permit to Operate for the following equipment:

S-13 Facility-Wide Wipe Cleaning Operation

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