



BAY AREA AIR QUALITY MANAGEMENT DISTRICT

PERMIT TO OPERATE

This document does not permit the holder to violate any BAAQMD regulation or any other law.

PERMIT EXPIRATION DATE
AUG 1, 2024

PLANT# 24876

Infinity Labs SD
1836 Stone Avenue
San Jose, CA 95125

Location: 1836 Stone Avenue
San Jose, CA 95125

S#	DESCRIPTION	[Schedule]	PAID
1	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A1 Ethylene Oxide Catalytic Bed, Electric Emissions at: P1 Stack	[G1]	3790
4	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A1 Ethylene Oxide Catalytic Bed, Electric Emissions at: P1 Stack	[G1]	3790
5	CHEM> Sterilization, medical equipment, Ethylene oxide Ethylene Oxide Sterilizer Abated by: A3 Unclassified Abatement Device Emissions at: P1 Stack	[G1]	3790

3 Permitted Sources

*** See attached Permit Conditions ***

The operating parameters described above are based on information supplied by permit holder and may differ from the limits set forth in the attached conditions of the Permit to Operate. The limits of operation in the permit conditions are not to be exceeded. Exceeding these limits is considered a violation of District regulations subject to enforcement action.



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*** PERMIT CONDITIONS ***

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Source#	Subject to Condition Numbers
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1	27253, 27253
4	27253, 27253
5	27253, 27253

The operating parameters described above are based on information supplied by permit holder and may differ from the limits set forth in the attached conditions of the Permit to Operate. The limits of operation in the permit conditions are not to be exceeded. Exceeding these limits is considered a violation of District regulations subject to enforcement action.



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COND# 27253 applies to S#'s 1, 1, 4, 4, 5, 5, 6, 7

Modified Permit Condition # 27253 applies to S-1, S-4, S-5, S-6, S-7, S-8, and S-9.

S-1 Ethylene Oxide Sterilizer

Make: 3M, Model: GS8X, Model Year: 2019

Serial # G000018

abated by

A-1 Catalytic Oxidizer

Make: 3M, Model: EtO Abator, Capacity: 50 CFM

Serial # 300171

S-4 Ethylene Oxide Sterilizer

Make: 3M, Model: GS8X, Model Year: 2019

Serial # G000053

abated by

A-1 Catalytic Oxidizer

Make: 3M, Model: EtO Abator, Capacity: 50 CFM

Serial # 300171

S-5 Ethylene Oxide Sterilizer

Make: 3M, Model: GS8X, Model Year: 2019

Serial # HA000011

abated by

A-3 Catalytic Oxidizer

Make: 3M, Model: EtO Abator, Capacity: 50 CFM

Serial # 300391

S-6 Ethylene Oxide Sterilizer

Make: 3M, Model: GS8X, Model Year: 2019

Serial # GA000041

abated by

A-3 Catalytic Oxidizer

Make: 3M, Model: EtO Abator, Capacity: 50 CFM

Serial # 300391

S-7 Ethylene Oxide Sterilizer

Make: 3M, Model: GS8X, Model Year: 2020

Serial # GB000076

abated by

A-4 Ethylene Oxide Abator (electric)

Make: 3M, Model: EtO Abator, Capacity: 50 CFM

Serial # 300219



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S-8 Ethylene Oxide Sterilizer
Make: 3M, Model: GS8X, Model Year: 2021
Serial # GB000094
abated by
A-2 Ethylene Oxide Abator (electric)
Make: 3M, Model: EtO Abator, Capacity: 50 CFM
Serial # 300172

S-9 Ethylene Oxide Sterilizer
Make: 3M, Model: GS8X, Model Year: 2021
Serial # GB000093
abated by
A-2 Ethylene Oxide Abator (electric)
Make: 3M, Model: EtO Abator, Capacity: 50 CFM
Serial # 300172

1. The Owner/Operator shall ensure the use of 100% ethylene oxide sterilant gas only. The use of any other sterilant gas is expressly prohibited under the terms of the permit unless prior approval and a Change of Condition is obtained in writing from the Bay Area Air Quality Management District.

[Basis: Cumulative Increase]

2. The Owner/Operator shall ensure that the total cumulative emissions of ethylene oxide sterilant gas from sources S1, S4, S5, S6, S7, S8, and S9 shall not exceed 6.00 pounds in any consecutive twelve-month period or 0.0011 pounds in any consecutive 60-minute period. [Basis: Regulation 2, Rule 5]

3. The Owner/Operator shall ensure that the total usage of ethylene oxide gas does not exceed 2,000 pounds in any consecutive twelve-month period for all seven sterilizers combined. The owner/operator shall ensure that the total ethylene oxide gas usage per sterilizer does not exceed 285.7 pounds in any consecutive twelve-month period. [Basis: Cumulative Increase]

4. The Owner/Operator shall ensure that the ethylene oxide emissions from Sources S-1 and S-4 are controlled by A-1 3M 50 cfm EtO Abator, Source S-5 and S-6 are controlled by A-3 3M 50 cfm EtO Abator, S-7 is controlled by A-4 3M Model 50 cfm EtO Abator, and S-8 and S-9 are controlled



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by A-2 3M Model 50 cfm EtO Abator. [Basis: Cumulative Increase; Regulation 2, Rule 5]

5. The Owner/Operator shall ensure that the sterilization cycle shall not be conducted unless ethylene oxide emissions are reduced by at least 99.9% during discharge of the sterilization phase, reduced by at least 95.0% during discharge of the aeration phase of each discrete cycle, and reduced by at least 99.7% averaged over the entire discharge cycle. At any time when the abatement system(s) is(are) unable to accept emissions from the sterilizer(s), the flow to the sterilizer(s) shall automatically cease. The catalyst beds shall be replaced as needed to comply with this requirement. [Basis: Cumulative Increase, "Ethylene Oxide ATCM for Sterilizers and Aerators", Section 93108, Title 17, CCR, Subsection (e), Regulation 2, Rule 5]

6. In order to demonstrate compliance with parts 2, 3, and 4, the Owner/Operator shall maintain a log of
a. sterilant gas purchases,
b. the date and time of each sterilization operation cycle,
c. the sterilizer utilized,
d. total pounds of ethylene oxide consumed by each sterilizer each month and for every 12-month period, and
e. records of catalyst bed replacement including date and the abatement device.

These records shall be retained on site for two years after the date of purchase or entry, and shall be made available for inspection by District staff upon request. [Basis: Cumulative Increase, Regulation 1, Rule 1-543]

7. To demonstrate compliance with these permit conditions, the Owner/Operator shall perform a District approved compliance source test (ARB Test Method 431) on S-6, S-7, S-8, and S-9 sterilizers within 60 days of sterilizer startup. The test shall include the sterilization cycle and the aeration cycle. The permit holder shall notify the Manager of the District's Source Test Section and the Director of the District's Engineering Division in writing at least seven(7) days prior to the test, to provide District staff the option of observing testing.



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Within 30 days of test completion a comprehensive report of the test results shall be submitted to the Manager of the District's Source Test Section for review and disposition. [Basis: "Ethylene Oxide ATCM for Sterilizers and Aerators", Section 93109, Title 17, CCR, Subsections (g) and (h)]

- 8. To demonstrate compliance with these permit conditions, the Owner/Operator also shall perform a District-approved compliance source test (ARB Test Method 431) on each sterilizer every two years. The test shall include the sterilization cycle and the aeration cycle. The Owner/Operator shall notify the Manager of the District's Source Test Section and the Director of The District's Engineering Division in writing at least Seven (7) days prior to the test, to provide District Staff the option of observing testing. Within 30 days of test completion a comprehensive report of the test results shall be submitted to the Manager of the District's Source Test Section for review and disposition. The first source test shall be due to the District on the second anniversary of the date of the Permit to Operate.

[Basis: "Ethylene Oxide ATCM for Sterilizers and Aerators", Section 93109, Title 17, CCR, Subsections (g) and (h)]

- 9. The Owner/Operator shall obtain approval from the District's Technical Services Division for the installation of stack sampling ports, and for all source testing procedures. The Owner/Operator shall notify the Engineering and Technical Divisions at least two weeks prior to any source test. [Basis: Regulation 1, Rule 1-501]

~~~~~ END OF CONDITIONS ~~~~~