



December 2021

**Determination of the Administrator of the Environmental Protection Agency
Under the Emergency Planning and Community Right-to-Know Act Section 313(b)(2)
to Apply the Requirements of EPCRA Section 313 to
Certain Contract Sterilization Facilities**

Recipients of this Determination:

1. Andersen Sterilizers, 3154 Caroline Drive, Haw River, NC 27258
2. Boston Scientific Corporation, 8 Industrial Drive, Coventry, RI 02816
3. ETO Sterilization-Plant #2, 2500 Brunswick Avenue, Linden, NJ 07036
4. Fuchs North America, 3800 Hampstead Mexico Road, Hampstead, MD 21074
5. International Sterilization Laboratory, 217 Sampey Road, Groveland, FL 34736
6. Isomedix Operations, Inc., 1435 Isomedix Place, El Paso, TX 79936
7. Isomedix Operations, Inc., 1175 Isuzu Parkway, Grand Prairie, TX 75050
8. Isomedix Operations, Inc., 435 Whitney Street, Northborough, MA 01532
9. LEMCO Ardmore, 3204 Hale Road, Ardmore, OK 73401
10. Long Island Sterilization, 175 Wireless Boulevard, Hauppauge, NY 11788
11. Medline Industries, 1160 South Northpoint Boulevard, Waukegan, IL 60085
12. Parter Medical Products Inc, 17115 Kingsview Avenue, Carson, CA 90746
13. Professional Contract Sterilization, Inc., 40 Myles Standish Boulevard, Taunton, MA 02780
14. Sterigenics U.S. LLC, 2971 Olympic Industrial Court SE, Suite 116, Atlanta, GA 30339
15. Sterigenics US, LLC, 18021 Withers Cove Park Drive, Charlotte, NC 28278
16. Sterigenics U.S. LLC, 1302 Avenue T, Grand Prairie, TX 75050
17. Sterigenics US, LLC, 687 Wanamaker Avenue, Ontario, CA 91761
18. Sterigenics US LLC, 84 Park Road, Queensbury, NY 12804
19. Sterigenics-Salt Lake City Facility, 5725 West Harold Gatty Drive, Salt Lake City, UT 84116
20. Sterigenics-Santa Teresa, NM, 2400 Airport Road, Santa Teresa, NM 88008

21. Sterigenics US, Inc., 4900 Gifford Avenue, Vernon, CA 90058
22. Sterilization Services of Tennessee, 2396 Florida Street, Memphis, TN 38109
23. STERIS Inc., 380 90th Avenue Northwest, Coon Rapids, MN 55433
24. Steris, Inc., 43425 Business Park Drive, Temecula, CA 92590
25. Steris Isomedix Services Inc, 7685 Saint Andrews Avenue, San Diego, CA 92154
26. Steris Isomedix Services Inc, 3459 S Clinton Avenue, South Plainfield, NJ 07080
27. STERIS-Isomedix Services, 2072 Southport Road, Spartanburg, SC 29306
28. Steritec, Inc., 1705 Enterprise Street, Athens, TX 75751
29. Trinity Sterile, Inc., 201 Kiley Drive, Salisbury, MD 21801

Pursuant to the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313(b)(2), the U.S. Environmental Protection Agency (EPA) is extending Toxics Release Inventory (TRI) reporting requirements to the facilities identified herein for ethylene oxide and, where specified, ethylene glycol. The requirement that the EPA is applying to these facilities requires the submission of certain chemical data if the facility manufactures, processes, or otherwise uses the chemical in amounts exceeding the respective threshold. Additional materials and information supporting this determination are available in the docket: EPA-HQ-OPPT-2021-0693.

This determination is organized as follows:

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I. BACKGROUND AND AUTHORITY

A. Toxics Release Inventory Reporting Requirement

EPCRA Section 313 requires owners and operators of covered facilities to submit certain data to the EPA TRI on the releases of listed toxic chemicals annually. *See* EPCRA § 313, 42 U.S.C. § 11023; 40 CFR 372. For a general overview of TRI, please visit the [EPA website \(https://www.epa.gov/tri\)](https://www.epa.gov/tri). In

addition, the Pollution Prevention Act (PPA) of 1990 requires owners and operators of TRI-covered facilities to report on additional waste management (*i.e.*, recycling, treatment, and energy recovery) and source reduction activities for these toxic chemicals. *See* PPA § 6607, 42 U.S.C. § 13106.

Specifically, EPCRA Section 313(a) requires any facility covered by a rule or determination under EPCRA Section 313(b) to report to TRI data on chemicals that it manufactures, processes, or otherwise uses in quantities exceeding the listed chemical's respective reporting threshold. *See* EPCRA § 313(a), 42 U.S.C. § 11023(a) (“[t]he owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under [EPCRA Section 313(g)] for each toxic chemical listed under [EPCRA Section 313(c)] that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by [EPCRA Section 313(f)] during the preceding calendar year at such facility.”). Thus, the owners or operators of such facilities are required to determine, each year, whether the facility meets the reporting thresholds for TRI chemicals. The owner or operator of each facility must conduct a threshold analysis for such chemical(s) and submit a TRI reporting form for the chemical(s) should the reporting threshold be exceeded for the given chemical(s).

Pursuant to 40 CFR 372.5, if the owner and operator of a facility are different persons, only one of them needs to report under 40 CFR 372.30, or provide a notice under 40 CFR 372.45, for each toxic chemical in a mixture or trade name product distributed from the facility. However, if neither submits a report or provides notice, the EPA will hold both persons liable under EPCRA Section 325(c), except as provided in 40 CFR 372.38(e) and 372.45(g).

B. Application to Additional Facilities Under EPCRA Section 313(b)(2)

EPCRA Section 313(b)(2) provides the EPA with the authority to extend the reporting requirements of EPCRA Section 313(a) to additional facilities per the Administrator's discretion:

The Administrator, on [their] own motion . . . , may apply the requirements of [EPCRA Section 313(a)] to the owners and operators of any particular facility that manufactures, processes, or otherwise uses a toxic chemical listed under [EPCRA Section 313(c)] if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.

Using this authority, the EPA may subject any particular facility to TRI reporting requirements for listed chemicals if the Administrator decides that such action is warranted based on the statutory factors provided in EPCRA Section 313(b)(2). Following such a determination, the facility is then subject to the TRI reporting requirements in EPCRA Section 313(a), regardless of its industry sector or number of full-time employee equivalents. *See* EPCRA § 313(a), (b)(1)-(2), 42 U.S.C. § 11023(a), (b)(1)-(2); 40 CFR 372.

C. Entities Covered by this Determination

The EPA Administrator is issuing this determination to apply TRI requirements to the facilities listed in Table 1 for ethylene oxide (CASRN: 75-21-8) and, where noted, ethylene glycol (CASRN: 107-21-1). The EPA rationale supporting this determination for each facility is outlined in Section II and Appendix

A, below.

This determination applies to the entire facility for each facility identified in Table 1, including all establishments. A TRI reporting facility can be comprised of multiple establishments—distinct and separate economic units—located on a single site (or contiguous or adjacent sites) if those establishments are owned or operated by the same person (*e.g.*, individual, trust, firm, joint stock company, corporation).

For the purposes of this determination, please refer to the definitions in EPCRA Section 329 and 40 CFR 372.3. Specifically, a few important definitions include:

Establishment means an economic unit, generally at a single physical location, where business is conducted or where services or industrial operations are performed.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person). A facility may contain more than one establishment.

Person means any individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or interstate body.

A TRI reporting facility can be comprised of multiple establishments—distinct and separate economic units—located on a single site (or contiguous or adjacent sites) if those establishments are owned or operated by the same person (*e.g.*, individual, trust, firm, joint stock company, corporation). This determination applies to the entire facility for each facility identified in Table 1, including all establishments.

II. DETERMINATION TO APPLY TRI REPORTING REQUIREMENTS TO PARTICULAR FACILITIES UNDER 313(b)(2)

EPCRA Section 313(b)(2) provides that the EPA may subject a facility to the TRI reporting requirements of EPCRA Section 313(a) “if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.”

The purpose of TRI is to provide governments and the public, including residents of communities surrounding covered facilities, with information on the releases and other waste management activities of listed toxic chemicals. After considering the factors for each facility as presented in Appendix A—including the toxicity of the chemicals, the facility’s proximity to population centers (including the number of schools and children under the age of five), the facility’s history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns), and the EPA estimates for

potential ethylene oxide quantities manufactured, processed, or otherwise used on-site¹—the EPA has determined that applying TRI reporting requirements to the facilities in Table 1 for ethylene oxide (and ethylene glycol, when noted) is warranted under EPCRA Section 313(b)(2). The EPA believes the public would benefit from increased information disclosure related to releases of these chemicals at these facilities. Therefore, pursuant to the EPA Administrator’s authority under EPCRA Section 313(b), the EPA hereby determines that it is appropriate to apply the requirements of EPCRA 313 to the facilities in Table 1 to the TRI reporting requirements for ethylene oxide (and ethylene glycol, when noted).

TABLE 1. Facilities to whom this determination applies.

Facility Name	Street Address	City	State	ZIP Code	Chemical(s)
Andersen Sterilizers	3154 Caroline Drive	Haw River	NC	27258	• Ethylene oxide (CASRN: 75-21-8)
Boston Scientific Corporation	8 Industrial Drive	Coventry	RI	02816	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
ETO Sterilization-Plant #2	2500 Brunswick Avenue	Linden	NJ	07036	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Fuchs North America	3800 Hampstead Mexico Road	Hampstead	MD	21074	• Ethylene oxide (CASRN: 75-21-8)
International Sterilization Laboratory	217 Sampey Road	Groveland	FL	34736	• Ethylene oxide (CASRN: 75-21-8)
Isomedix Operations, Inc.	1435 Isomedix Place	El Paso	TX	79936	• Ethylene oxide (CASRN: 75-21-8)
Isomedix Operations, Inc.	1175 Isuzu Parkway	Grand Prairie	TX	75050	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Isomedix Operations, Inc.	435 Whitney Street	Northborough	MA	01532	• Ethylene oxide (CASRN: 75-21-8)
LEMCO Ardmore	3204 Hale Road	Ardmore	OK	73401	• Ethylene oxide (CASRN: 75-21-8)

¹ EPA does not believe that EPCRA Section 313(b)(2) requires that a facility currently meet the TRI reporting thresholds for this determination to be warranted. However, EPA does believe that considering the quantity of ethylene oxide or ethylene glycol potentially manufactured, processed, or otherwise used on-site is appropriate in determining whether this action is warranted.

Long Island Sterilization	175 Wireless Boulevard	Hauppauge	NY	11788	• Ethylene oxide (CASRN: 75-21-8)
Medline Industries	1160 South Northpoint Boulevard	Waukegan	IL	60085	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Parter Medical Products Inc	17115 Kingsview Avenue	Carson	CA	90746	• Ethylene oxide (CASRN: 75-21-8)
Professional Contract Sterilization, Inc.	40 Myles Standish Boulevard	Taunton	MA	02780	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics U.S. LLC	2971 Olympic Industrial Court SE, Suite 116	Atlanta	GA	30339	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics US, LLC	18021 Withers Cove Park Drive	Charlotte	NC	28278	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics U.S. LLC	1302 Avenue T	Grand Prairie	TX	75050	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics US, LLC	687 Wanamaker Avenue	Ontario	CA	91761	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics US LLC	84 Park Road	Queensbury	NY	12804	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics - Salt Lake City Facility	5725 West Harold Gatty Drive	Salt Lake City	UT	84116	• Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)

Sterigenics-Santa Teresa, NM	2400 Airport Road	Santa Teresa	NM	88008	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterigenics US, Inc.	4900 Gifford Avenue	Vernon	CA	90058	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Sterilization Services of Tennessee	2396 Florida Street	Memphis	TN	38109	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
STERIS Inc.	380 90th Avenue Northwest	Coon Rapids	MN	55433	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8)
Steris, Inc.	43425 Business Park Drive	Temecula	CA	92590	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8)
Steris Isomedix Services Inc	7685 Saint Andrews Avenue	San Diego	CA	92154	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
Steris Isomedix Services Inc	3459 S Clinton Avenue	South Plainfield	NJ	07080	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8) • Ethylene glycol (CASRN: 107-21-1)
STERIS-Isomedix Services	2072 Southport Road	Spartanburg	SC	29306	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8)
Steritec, Inc.	1705 Enterprise Street	Athens	TX	75751	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8)
Trinity Sterile, Inc.	201 Kiley Drive	Salisbury	MD	21801	<ul style="list-style-type: none"> • Ethylene oxide (CASRN: 75-21-8)

Nothing in this determination should be read as limiting the scope of the “facility” subject to this determination to a single establishment listed in Table 1, should additional buildings, equipment, or sites on adjacent and/or contiguous land with a common operator or operator also fall within the scope of the facility. *See* EPCRA § 329(4), 42 U.S.C. § 11049(4); 40 CFR 372.3.

III. CONSEQUENCES OF THIS DECISION: REPORTING AND RECORDKEEPING UNDER EPCRA SECTION 313(a)

The EPA decision to apply the requirements of EPCRA to these facilities makes the owner and operator

of each facility specified in Table 1 subject to TRI reporting requirements under EPCRA Section 313. *See* EPCRA § 313, 42 U.S.C. § 110023; 40 CFR 372. If that facility subsequently manufactures, processes, or otherwise uses ethylene oxide (or ethylene glycol, where noted) above the activity thresholds, EPCRA Section 313(a) would require the facility's current owner or operator to report for that chemical pursuant to the statute and the EPA implementing regulations. Nothing in this determination alters the requirements of EPCRA Sections 313(a) and 313(g) or requires an owner or operator to report if the facility does not meet the chemical activity threshold requirements in EPCRA Section 313(f) or 40 CFR 372, subpart. B. This determination under EPCRA Section 313(b)(2) applies the TRI reporting requirements in EPCRA Section 313(a) to the facilities listed in Table 1, without regard to their industry sector (*i.e.*, North American Industry Classification System (NAICS) code) or the number of full-time employee-equivalents.

A. Consequences of Failing to Comply with EPCRA Section 313(a)

Failure to comply with any reporting requirements of EPCRA Section 313 is a violation of EPCRA and could subject you to civil and administrative penalties under EPCRA Section 325. EPCRA § 325, 42 U.S.C. § 11045; 40 C.F.R. pt. 19 (implementing civil penalties adjustments). Each day a facility fails to meet any of the requirements constitutes a separate violation of the specific requirement. Submission of false information to the EPA or knowing failure to file an EPCRA Section 313 report may also be subject to criminal penalties under 18 U.S.C. § 1001.

B. Paperwork Reduction Act Notice

The current collection of information under the EPA TRI regulations is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. *See* OMB Control No. 2070-0212. The EPA is currently revising its information collection request (ICR) for the TRI regulations to account for potential reporting by additional facilities under EPCRA Section 313(b)(2), specifically ethylene oxide-using facilities (some of which also include ethylene glycol, where noted). These revisions are currently pending approval with OMB. The normal clearance procedures under the PRA require agencies to provide a 60-day public comment opportunity before submitting an ICR to OMB for review and approval. The OMB review and approval process involves another mandated 30 days for additional public comment. The 60-day public comment period for collecting information under this discretionary authority began on November 15, 2021. *See* Proposed Revisions to an Existing Collection: Toxic Chemical Release Reporting, 86 Fed. Reg. 63025.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The annual public burden related to the Form R is estimated to be 35.7 hours per response for a facility filing a report on one chemical. The annual public burden related to the Form A is estimated to average 21.96 hours per response for a facility filing a report on one chemical. Under the PRA, burden is defined at 5 CFR 1320.3(b). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed TRI form to this address.

While the EPA cannot enforce recordkeeping from entities subject to this determination pursuant to its

TRI regulations until OMB has approved the ICR, the EPA reminds covered entities that persons subject to the statutory reporting and recordkeeping requirements in EPCRA Sections 313(a) and 313(g) are nevertheless subject to enforcement under EPCRA Section 325(c)(1) should they fail to comply with those requirements. *See* 5 CFR 1320.6(e) (observing that penalties protections under 5 CFR 1320.6(a) do not “preclude the imposition of a penalty on a person for failing to comply with a collection of information that is imposed on the person by statute”). The EPA anticipates that OMB will approve the ICR in Spring 2022.

IV. FOR FURTHER INFORMATION CONTACT

For technical information contact: Stephanie Griffin, Data Collection Branch, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-1463; email address: griffin.stephanie@epa.gov.

For general TRI support and contacts, see the TRI Program Contacts webpage:
<https://www.epa.gov/toxics-release-inventory-tri-program/forms/tri-program-contacts>.

V. SIGNATURE

Under the authority of EPCRA Section 313(b)(2) the United States Environmental Protection Agency hereby issues this Determination to take effect on the date of my signature

Dated: DEC 16 2021.

Michael S. Regan,



Administrator.

Enclosures:

Appendix A: Factors for Extending Reporting Requirements to the Identified Facilities

Appendix B: References

APPENDIX A.
FACTORS FOR EXTENDING REPORTING REQUIREMENTS
TO THE IDENTIFIED FACILITIES

1. Andersen Sterilizers, 3154 Caroline Drive, Haw River, NC 27258

- FRS ID: 110012475437
- TRI Facility Identification Number: 27258HWNDR5344N
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0694
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 12,240 within a five-mile radius of this facility, including approximately 708 children under five years old (Ref. 7). The EPA also estimated there are at least 3 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 2001 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a

five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	34	34	32
NATA respiratory hazard index	34	35	32
NATA diesel particulate matter (PM)	34	37	40
PM 2.5	34	34	36
Ozone	35	31	36
Traffic proximity	39	41	47
Proximity to Risk Management Plan (RMP) sites	26	30	34

E. Facility worker concerns

Some evident – from historic occupational studies of workers at ethylene oxide facilities indicates that exposure to high levels of ethylene oxide may cause adverse health effects on works, including an increasing rate of miscarriages in female workers (Ref. 6)

F. Additional information

Andersen Sterilizers responded to the EPA letter dated October 1 to clarify the names and addresses of the establishments on sites across the street from each other. While Andersen Sterilizers indicated the establishment at 3154 Caroline Drive, Haw River, NC, does not conduct ethylene oxide sterilization services, they confirmed they are manufacturers of ethylene oxide sterilizers and refill kits, and ethylene oxide is present on-site. Although this facility indicated they no longer provide ethylene oxide contract sterilization services, their manufacture of such sterilization devices and refill kits remains of interest to the EPA.

Additionally, Andersen Sterilizers confirmed that the company listed as “Andersen Products” at 3202 Caroline Drive is a former sterilization facility, across a public right-of-way from Andersen Sterilizers, and the two establishments have shared ownership. Based on this information from Andersen Sterilizers, The EPA believes that Andersen Sterilizers and Andersen Products form a multi-establishment facility under the definition of “facility” under EPCRA; the entire facility is covered by this determination.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Andersen Sterilizers (including Andersen Products) warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility.

Additionally, current activities at this facility involving ethylene oxide as described by Andersen Sterilizers (including the manufacturing of ethylene oxide sterilizers and refill kits) support this

determination under EPCRA Section 313(b)(2).

2. Boston Scientific Corporation, 8 Industrial Drive, Coventry, RI 02816

- FRS ID: 110032604938
- TRI Facility Identification Number: 02816CSMDF8INDU
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0696
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 71,144 within a five-mile radius of this facility, including approximately 3,557 children under five years old (Ref. 7). The EPA also estimated there are at least 16 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide, and 2005 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the

80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	28	31	23
NATA respiratory hazard index	29	31	26
NATA diesel particulate matter (PM)	31	24	20
PM 2.5	28	30	26
Ozone	27	28	18
Traffic proximity	30	29	15
Proximity to Risk Management Plan (RMP) sites	16	8	7

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

Boston Scientific responded to the EPA October 1 letter to confirm that they have and will continue to comply with any applicable regulatory requirements from the EPA. Additionally, Boston Scientific stated that they do not consider their facility to be a “contract sterilizer” as they exclusively sterilize company-manufactured products. As defined by the FDA, a “contract sterilizer” includes any establishment which provides a contractual service to sterilize an FDA-regulated product (Ref. 8); further, the FDA’s Establishment Registration & Device Listing database includes mentions of the Coventry, RI, facility as both a manufacturer and contract sterilizer (Ref. 9). Therefore, the EPA believes that Boston Scientific is a “contract sterilizer.” Additionally, the EPA notes that the use of its authority at EPCRA Section 313(b)(2) does not hinge on a facility’s industry self-classification.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Boston Scientific Corporation

warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, current sterilization activities at this facility involving ethylene oxide as described by Boston Scientific support this determination under EPCRA Section 313(b)(2).

3. ETO Sterilization-Plant #2, 2500 Brunswick Avenue, Linden, NJ 07036

- FRS ID: 110000318567
- TRI Facility Identification Number: 07036TSTRL2500B
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0697
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 500,724 within a five-mile radius of this facility, including approximately 30,043 children under five years old (Ref. 7). The EPA also estimated there are at least 156 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2009 for ethylene oxide, and 2009 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7).

This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	77	72	75
NATA respiratory hazard index	78	73	77
NATA diesel particulate matter (PM)	82	74	86
PM 2.5	77	74	74
Ozone	76	72	73
Traffic proximity	87	81	88
Proximity to Risk Management Plan (RMP) sites	89	92	89

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that ETO Sterilization-Plant #2 warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2).

4. Fuchs North America, 3800 Hampstead Mexico Road, Hampstead, MD 21074

- FRS ID: 110070234075
- TRI Facility Identification Number: N/A

- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0698
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 27,243 within a five-mile radius of this facility, including approximately 1,090 children under five years old (Ref. 7). The EPA also estimated there are at least 9 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	16	19	15
NATA respiratory hazard index	18	19	16
NATA diesel particulate matter (PM)	26	24	17
PM 2.5	12	16	12
Ozone	12	14	12
Traffic proximity	22	26	20
Proximity to Risk Management Plan (RMP) sites	37	47	40

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Additional information

In response to the EPA letter dated October 1, Fuchs North America confirmed they use ethylene oxide for spice and herb treatment and are able to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting.

F. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility's proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Fuchs North America warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, and there are limited public data on the facility's history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, Fuchs North America acknowledges that there are current activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

5. International Sterilization Laboratory, 217 Sampey Road, Groveland, FL 34736

- FRS ID: 110001742419
- TRI Facility Identification Number: N/A
- Chemical(s) Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0699
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 26,912 within a five-mile radius of this facility, including approximately 1,615 children under five years old (Ref. 7). The EPA also estimated there are at least 9 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	53	59	63
NATA respiratory hazard index	53	60	64
NATA diesel particulate matter (PM)	50	58	61
PM 2.5	53	59	63
Ozone	53	59	62
Traffic proximity	60	71	69
Proximity to Risk Management Plan (RMP) sites	56	66	67

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that International Sterilization Laboratory warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, and there are limited public data on the facility’s history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility.

6. Isomedix Operations, Inc., 1435 Isomedix Place, El Paso, TX 79936

- FRS IDs: 110014421438; 110056966083
- TRI Facility Identification Number: 79936SMDXN1435I

- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0700
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 280,699 within a five-mile radius of this facility, including approximately 19,649 children under five years old (Ref. 7). The EPA also estimated there are at least 103 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	83	87	93

NATA respiratory hazard index	84	87	91
NATA diesel particulate matter (PM)	82	86	89
PM 2.5	80	85	91
Ozone	89	92	95
Traffic proximity	86	89	88
Proximity to Risk Management Plan (RMP) sites	80	84	90

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

F. Additional information

STERIS responded to the EPA letter dated October 1 on behalf of this facility. STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS' concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Isomedix Operations, Inc., warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

7. Isomedix Operations, Inc., 1175 Isuzu Pkwy, Grand Prairie, TX 75050

- FRS ID: 110002131014
- TRI Facility Identification Number: 75050CSMDF1175I
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0701
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 236,884 within a five-mile radius of this facility, including approximately 18,951 children under five years old (Ref. 7). The EPA also estimated there are at least 64 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide, and 2005 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	65	71	82
NATA respiratory hazard index	66	72	81
NATA diesel particulate matter (PM)	72	78	83
PM 2.5	64	71	81
Ozone	65	71	82
Traffic proximity	86	89	88
Proximity to Risk Management Plan (RMP) sites	72	78	86

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS’ concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Isomedix Operations, Inc., warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

8. Isomedix Operation, Inc., 435 Whitney Street, Northborough, MA 01532

- FRS ID: 110000498168
- TRI Facility Identification Number: 01532SMDXP435WH
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0702
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 73,266 within a five-mile radius of this facility, including approximately 3,663 children under five years old (Ref. 7). The EPA also estimated there are at least 30 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	28	27	21
NATA respiratory hazard index	33	31	25
NATA diesel particulate matter (PM)	37	31	24
PM 2.5	35	35	29
Ozone	34	34	22
Traffic proximity	38	26	13
Proximity to Risk Management Plan (RMP) sites	21	18	14

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS’ concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Isomedix Operations, Inc., warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

9. LEMCO Ardmore, 3204 Hale Road, Ardmore, OK 73401

- FRS ID: 110001638032
- TRI Facility Identification Number: N/A

- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0703
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 25,712 within a five-mile radius of this facility, including approximately 1,800 children under five years old (Ref. 7). The EPA also estimated there are at least 11 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	55	40	57
NATA respiratory hazard index	55	41	57
NATA diesel particulate matter (PM)	55	40	57
PM 2.5	55	40	57
Ozone	54	40	57
Traffic proximity	66	46	61
Proximity to Risk Management Plan (RMP) sites	66	47	61

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility's proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that LEMCO Ardmore warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, and there are limited public data on the facility's history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility.

10. Long Island Sterilization, 175 Wireless Boulevard, Hauppauge, NY 11788

- FRS ID: 110019608735
- TRI Facility Identification Number: N/A
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0704
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 260,591 within a five-mile radius of this facility, including approximately 15,635 children under five years old (Ref. 7). The EPA also estimated there are at least 72 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the

80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	58	60	62
NATA respiratory hazard index	58	60	62
NATA diesel particulate matter (PM)	59	61	66
PM 2.5	59	60	62
Ozone	59	61	63
Traffic proximity	62	64	71
Proximity to Risk Management Plan (RMP) sites	68	69	70

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Long Island Sterilization warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, and there are limited public data on the facility’s history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility.

11. Medline Industries, 1160 South Northpoint Boulevard, Waukegan, IL 60085

- FRS ID: 110018354010
- TRI Facility Identification Number: 60085CSMDF1160N
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0705
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment,

among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 167,339 within a five-mile radius of this facility, including approximately 10,040 children under five years old (Ref. 7). The EPA also estimated there are at least 55 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide, and 2005 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	95	98	92

NATA respiratory hazard index	79	89	76
NATA diesel particulate matter (PM)	78	89	81
PM 2.5	82	90	80
Ozone	85	92	83
Traffic proximity	79	85	74
Proximity to Risk Management Plan (RMP) sites	85	93	89

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Medline Industries warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2).

12. Parter Medical Products Inc., 17115 Kingsview Avenue, Carson, CA 90746

- FRS ID: 110021034780
- TRI Facility Identification Number: N/A
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0707
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 702,853 within a five-mile radius of this

facility, including approximately 49,200 children under five years old (Ref. 7). The EPA also estimated there are at least 209 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	77	79	90
NATA respiratory hazard index	77	79	91
NATA diesel particulate matter (PM)	87	87	92
PM 2.5	79	82	93
Ozone	72	73	89
Traffic proximity	90	92	97
Proximity to Risk Management Plan (RMP) sites	88	89	95

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Parter Medical Products warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While there are limited public data on the facility’s history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility.

13. Professional Contract Sterilization, Inc., 40 Myles Standish Boulevard, Taunton, MA 02780

- FRS ID: 110000882466
- TRI Facility Identification Number: 02780PRFSS40MYL
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0708
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 69,653 within a five-mile radius of this facility, including approximately 3,483 children under five years old (Ref. 7). The EPA also estimated there are at least 18 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 1992 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	40	39	28
NATA respiratory hazard index	41	39	31
NATA diesel particulate matter (PM)	43	37	27
PM 2.5	36	37	30
Ozone	37	38	24
Traffic proximity	57	44	25
Proximity to Risk Management Plan (RMP) sites	17	14	11

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Professional Contract Sterilization, Inc., warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility.

14. Sterilization Services of Tennessee, 2396 Florida Street, Memphis, TN 38109

- FRS ID: 110000374121
- TRI Facility Identification Number: 38109STRLZ2396F
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0717
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment,

among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 134,996 within a five-mile radius of this facility, including approximately 8,100 children under five years old (Ref. 7). The EPA also estimated there are at least 73 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2002 for ethylene oxide, and 2002 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	92	84	87

NATA respiratory hazard index	93	85	88
NATA diesel particulate matter (PM)	92	87	87
PM 2.5	91	84	85
Ozone	91	86	86
Traffic proximity	96	91	88
Proximity to Risk Management Plan (RMP) sites	91	85	84

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility’s proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterilization Services of Tennessee warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2).

15. Sterigenics U.S. LLC, 2971 Olympic Industrial Court SE, Suite 116, Atlanta, GA 30339

- FRS ID: 110000355963
- TRI Facility Identification Number: 30080GRFFT2973O
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0709
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human

health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 201,535 within a five-mile radius of this facility, including approximately 12,092 children under five years old (Ref. 7). The EPA also estimated there are at least 50 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	54	65	69
NATA respiratory hazard index	55	65	69
NATA diesel particulate matter (PM)	64	71	71
PM 2.5	54	64	67
Ozone	54	64	66
Traffic proximity	70	75	72
Proximity to Risk Management Plan (RMP) sites	74	80	79

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics U.S. LLC warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

16. Sterigenics US, LLC, 18021 Withers Cove Park Drive, Charlotte, NC 28278

- FRS ID: 110000349720
- TRI Facility Identification Number: 28278GRFFT10801
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0710
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2).

The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 88,448 within a five-mile radius of this facility, including approximately 6,191 children under five years old (Ref. 7). The EPA also estimated there are at least 17 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	76	72	76
NATA respiratory hazard index	73	69	73
NATA diesel particulate matter (PM)	82	75	75
PM 2.5	69	66	69
Ozone	68	68	69
Traffic proximity	86	80	76
Proximity to Risk Management Plan (RMP) sites	93	87	86

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics US, LLC warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

17. Sterigenics U.S. LLC, 1302 Avenue T, Grand Prairie, TX 75050

- FRS ID: 110015320543
- TRI Facility Identification Number: 75050BSNCX132AV
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0711
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2).

The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 243,218 within a five-mile radius of this facility, including approximately 19,457 children under five years old (Ref. 7). The EPA also estimated there are at least 76 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, The EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	69	75	84
NATA respiratory hazard index	70	75	83
NATA diesel particulate matter (PM)	76	81	85
PM 2.5	67	74	84
Ozone	69	75	84
Traffic proximity	87	90	89
Proximity to Risk Management Plan (RMP) sites	77	81	88

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics U.S. LLC warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

18. Sterigenics US, LLC, 687 Wanamaker Ave, Ontario, CA 91761

- FRS ID: 110000478162
- TRI Facility Identification Number: 91761GRFFT687SW
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0712
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2).

The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 239,301 within a five-mile radius of this facility, including approximately 16,751 children under five years old (Ref. 7). The EPA also estimated there are at least 76 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	77	79	90
NATA respiratory hazard index	76	78	90
NATA diesel particulate matter (PM)	85	85	91
PM 2.5	80	83	93
Ozone	84	85	95
Traffic proximity	73	77	92
Proximity to Risk Management Plan (RMP) sites	86	88	95

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics US, LLC warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

19. Sterigenics US LLC, 84 Park Road, Queensbury, NY 12804

- FRS ID: 110000499425
- TRI Facility Identification Number: 12801GRFFT27PAR
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0713
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2).

The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 47,634 within a five-mile radius of this facility, including approximately 2,858 children under five years old (Ref. 7). The EPA also estimated there are at least 20 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	16	19	22
NATA respiratory hazard index	18	21	24
NATA diesel particulate matter (PM)	27	30	24
PM 2.5	19	22	27
Ozone	20	22	25
Traffic proximity	21	22	16
Proximity to Risk Management Plan (RMP) sites	2	2	4

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Sterigenics US LLC warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

20. Sterigenics--Salt Lake City Facility, 5725 West Harold Gatty Drive, Salt Lake City, UT 84116

- FRS ID: 110000469528
- TRI Facility Identification Number: 84116SRXMD5725W
- Chemicals Identified: Ethylene oxide; Ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0714
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human

health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref 2). The National Institute for Occupational Safety and Health also note “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 22,247 within a five-mile radius of this facility, including approximately 2,225 children under five years old (Ref. 7). The EPA also estimated there are at least 11 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	98	97	86
NATA respiratory hazard index	98	97	87
NATA diesel particulate matter (PM)	97	98	95
PM 2.5	98	97	86
Ozone	97	97	92
Traffic proximity	97	97	92
Proximity to Risk Management Plan (RMP) sites	98	97	93

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that they provide certain information related to the usage and air emissions of ethylene oxide from their facilities to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics—Salt Lake City Facility warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

21. Sterigenics-Santa Teresa, NM, 2400 Airport Road, Santa Teresa, NM 88008

- FRS ID: 110000472541
- TRI Facility Identification Number: 88008GRFFT2400A
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0715
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human

health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 19,642 within a five-mile radius of this facility, including approximately 1,571 children under five years old (Ref. 7). The EPA also estimated there are at least 6 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	99	99	99
NATA respiratory hazard index	97	93	94
NATA diesel particulate matter (PM)	79	71	78
PM 2.5	97	90	94
Ozone	97	97	98
Traffic proximity	77	77	79
Proximity to Risk Management Plan (RMP) sites	99	93	96

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics-Santa Teresa, NM warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

22. Sterigenics US, Inc., 4900 Gifford Avenue, Vernon, CA 90058

- FRS IDs: 110012150493; 110012150509
- TRI Facility Identification Numbers: 90058GRFFT4801E; 90058GRFFT4900G
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0716
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human

health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 961,478 within a five-mile radius of this facility, including approximately 67,303 children under five years old (Ref. 7). The EPA also estimated there are at least 324 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2016 for ethylene oxide, and 2016 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	89	90	95
NATA respiratory hazard index	88	89	95
NATA diesel particulate matter (PM)	93	93	96
PM 2.5	87	89	96
Ozone	82	83	94
Traffic proximity	93	94	98
Proximity to Risk Management Plan (RMP) sites	97	97	99

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

In response to the EPA letter dated October 1, Sterigenics confirmed they are willing to report to TRI, should the EPA decide to exercise its discretionary authority for TRI reporting. Further, Sterigenics notes that certain information related to the usage and air emissions of ethylene oxide from their facilities have been provided to other EPA programs and to state environmental protection agencies.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Sterigenics US, Inc. warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, Sterigenics acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

23. STERIS Inc., 380 90th Avenue Northwest, Coon Rapids, MN 55433

- FRS ID: 110008821677
- TRI Facility Identification Number: 55433QLTYS38090
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0718
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 217,774 within a five-mile radius of this facility, including approximately 15,244 children under five years old (Ref. 7). The EPA also estimated

there are at least 96 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility's history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	60	54	43
NATA respiratory hazard index	58	52	43
NATA diesel particulate matter (PM)	51	49	37
PM 2.5	67	61	46
Ozone	70	61	46
Traffic proximity	49	44	35
Proximity to Risk Management Plan (RMP) sites	49	37	25

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS’ concerns are rooted in both their perceived accuracy of the NATA data and its

origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that STERIS Inc. warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, current sterilization activities at this facility involving ethylene oxide as described by STERIS support this determination under EPCRA Section 313(b)(2).

24. Steris Isomedix Services Inc., 7685 Saint Andrews Avenue, San Diego, CA 92154

- FRS IDs: 110006625474; 110070467989
- TRI Facility Identification Number: 92154CSMDF7685S
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0720
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is "clear evidence" of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health "systemic ethylene glycol toxicity can occur through ingestion" (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 156,742 within a five-mile radius of this facility, including approximately 10,972 children under five years old (Ref. 7). The EPA also estimated there are at least 36 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility's history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide, and 2005 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	98	98	99
NATA respiratory hazard index	97	97	98
NATA diesel particulate matter (PM)	90	90	94
PM 2.5	97	97	99
Ozone	96	96	99
Traffic proximity	85	87	96
Proximity to Risk Management Plan (RMP) sites	73	76	88

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS' concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Steris Isomedix Services Inc. warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

25. Steris Isomedix Services Inc., 3459 S Clinton Avenue, South Plainfield, NJ 07080

- FRS ID: 110041057389
- TRI Facility Identification Number: 07080CSMDF3459S
- Chemicals Identified: Ethylene oxide; ethylene glycol
- Docket ID: EPA-HQ-OPPT-2021-0721
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemicals

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is "clear evidence" of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. The EPA IRIS Program found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage (Ref. 2). The National Institute for Occupational Safety and Health “systemic ethylene glycol toxicity can occur through ingestion” (Ref. 3).

B. Proximity to population centers

The EPA determined there is a population of approximately 303,229 within a five-mile radius of this facility, including approximately 18,194 children under five years old (Ref. 7). The EPA also estimated there are at least 121 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide and ethylene glycol to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide, and 2005 for ethylene glycol. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide and ethylene glycol.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	75	70	73
NATA respiratory hazard index	74	69	72
NATA diesel particulate matter (PM)	72	67	76
PM 2.5	75	72	73
Ozone	76	71	73
Traffic proximity	76	70	79
Proximity to Risk Management Plan (RMP) sites	81	82	81

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

Additionally, studies suggest that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation (Ref. 2).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS' concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of both ethylene oxide and ethylene glycol, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Steris Isomedix Services Inc. warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

26. Steris, Inc., 43425 Business Park Drive, Temecula, CA 92590

- FRS IDs: 110000479740; 110070452878
- TRI Facility Identification Number: 92590SMDXP43425
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0719
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment,

among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 155,674 within a five-mile radius of this facility, including approximately 10,897 children under five years old (Ref. 7). The EPA also estimated there are at least 45 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility’s history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	33	35	58
NATA respiratory hazard index	33	36	59
NATA diesel particulate matter (PM)	37	40	62
PM 2.5	32	36	58
Ozone	32	35	58
Traffic proximity	44	50	74
Proximity to Risk Management Plan (RMP) sites	39	43	65

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS' concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Steris, Inc. warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

27. STERIS-Isomedix Services, 2072 Southport Road, Spartanburg, SC 29306

- FRS ID: 110000352706
- TRI Facility Identification Number: 29301SMDXN2072S
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0722
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a

mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 65,263 within a five-mile radius of this facility, including approximately 3,916 children under five years old (Ref. 7). The EPA also estimated there are at least 28 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Facility's history of releases

This facility previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 2005 for ethylene oxide. The EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide.

D. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	67	64	68
NATA respiratory hazard index	66	63	67
NATA diesel particulate matter (PM)	76	68	69
PM 2.5	66	63	66
Ozone	66	63	66
Traffic proximity	79	69	67
Proximity to Risk Management Plan (RMP) sites	79	71	71

E. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an

increased rate of miscarriages in female workers (Ref. 6).

F. Additional information

Additionally, STERIS voiced concern with the NATA data referenced in the October 1 letter. Specifically, STERIS' concerns are rooted in both their perceived accuracy of the NATA data and its origin. The EPA notes that there is a separate channel in which the EPA, other regulators, and industry, including STERIS, are engaged on this topic, and reviewing data submitted for the EPA Air Toxics Data Update. However, for the purpose of reviewing various facility-specific factors relevant under EPCRA Section 313(b)(2), the EPA notes that there are additional environmental indicators not stemming from NATA that were reviewed in the EJSCREEN assessment; neither the environmental justice screening nor the overall decision to exercise this discretionary authority hinge solely on the NATA-sourced environmental indicators.

STERIS also confirmed that, should the EPA decide to exercise its discretionary authority to require this facility to report to TRI, they would be prepared to do so.

G. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility's proximity to population centers (including the number of schools and children under the age of five), its history of releases (as determined through past TRI reporting), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that STERIS-Isomedix Services warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, the EPA believes that, on balance, the other factors support the application of this authority to this facility. Additionally, STERIS acknowledges that there are current sterilization activities at this facility involving ethylene oxide, which supports this determination under EPCRA Section 313(b)(2).

28. Steritec, Inc., 1705 Enterprise Street, Athens, TX 75751

- FRS ID: 110035029313
- TRI Facility Identification Number: N/A
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0723
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is "clear evidence" of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 17,025 within a five-mile radius of this

facility, including approximately 1,362 children under five years old (Ref. 7). The EPA also estimated there are at least 7 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	47	53	68
NATA respiratory hazard index	47	53	67
NATA diesel particulate matter (PM)	47	53	66
PM 2.5	47	53	68
Ozone	47	53	67
Traffic proximity	60	66	72
Proximity to Risk Management Plan (RMP) sites	57	64	75

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers), the EPA has determined that Steritec warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While all EJSCREEN indices are comparatively low, and there are limited public data on the facility’s history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility.

29. Trinity Sterile, Inc., 201 Kiley Drive, Salisbury, MD 21801

- FRS ID: 110001260803
- TRI Facility Identification Number: N/A
- Chemical Identified: Ethylene oxide
- Docket ID: EPA-HQ-OPPT-2021-0724
- Factors for Extending TRI Reporting Requirements:

A. Toxicity of the chemical

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, the EPA Integrated Risk Information System (IRIS) Program updated its cancer assessment for ethylene oxide and characterized the chemical as “carcinogenic to humans” by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is “clear evidence” of ethylene oxide’s genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity (Ref. 1).

B. Proximity to population centers

The EPA determined there is a population of approximately 64,196 within a five-mile radius of this facility, including approximately 4,494 children under five years old (Ref. 7). The EPA also estimated there are at least 27 schools within a five-mile radius of the facility (Refs. 4 and 5). Because ethylene oxide is mutagenic, and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns the EPA (Ref. 6).

C. Environmental justice concerns

The EPA maintains an online environmental justice screening and mapping tool, EJSCREEN (Ref. 7). This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and the EPA does not interpret these results as a risk assessment. For early applications of EJSCREEN, the EPA identified the 80th percentile filter as an initial starting point in identifying potential environmental justice areas for further review.

Because the EPA lists ethylene oxide as “carcinogenic to humans” by the inhalation route of exposure, the EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, the EPA region, or U.S.:

Environmental Justice Index	Percentile in State	Percentile in EPA Region	Percentile in U.S.
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	62	77	67
NATA respiratory hazard index	61	76	67
NATA diesel particulate matter (PM)	59	76	68
PM 2.5	63	77	68

Ozone	64	78	69
Traffic proximity	72	82	77
Proximity to Risk Management Plan (RMP) sites	86	89	82

D. Facility worker concerns

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers (Ref. 6).

E. Conclusion of EPCRA Section 313(b)(2) determination

Based on the toxicity of ethylene oxide, this facility’s proximity to population centers (including the number of schools and children under the age of five), and other factors the EPA Administrator deems appropriate (including concerns for facility workers and potential environmental justice concerns, as shown through air-related EJSCREEN scores), the EPA has determined that Trinity Sterile, Inc. warrants extending reporting requirements under EPCRA Section 313(a), per the EPA authority at EPCRA Section 313(b)(2). While there are limited public data on the facility’s history of ethylene oxide releases (as determined through past TRI reporting), the EPA believes that, on balance, the other factors support the application of this authority to this facility.

APPENDIX B. REFERENCES

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