



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 23, 2021

Via Certified Mail and Email; Return Receipt Requested

Steve Walter
VP Sterilization Services
International Sterilization Laboratory
217 Sampey Road
Groveland, FL 34736

Subject: EPCRA Section 313(b)(2) Determination
FRS ID: 110001742419
Chemical: Ethylene Oxide

Dear Steve Walter,

On October 1, 2021, the U.S. Environmental Protection Agency (EPA) sent a letter to you about potentially exercising its discretionary authority under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313(b)(2) to extend Toxics Release Inventory (TRI) reporting requirements of EPCRA Section 313(a) to your facility. **After careful deliberation, EPA has decided to use this discretionary authority to extend TRI reporting requirements to the facility listed above for ethylene oxide.** On December 16, 2021, EPA Administrator Michael Regan signed a determination under EPCRA Section 313(b)(2) extending TRI reporting requirements to several facilities, for specified chemicals, and laying out EPA's rationale for this action. EPA has attached a copy of that determination to this letter.

Going forward, this facility is subject to the reporting and recordkeeping requirements of EPCRA Section 313(a). The facility must determine whether their on-site activities (manufacturing, processing, and otherwise using) that involve ethylene oxide meet the TRI chemical reporting threshold quantities. Under EPCRA Section 313(a), should this facility meet a chemical activity threshold for ethylene oxide, the owner or operator must report releases, other waste management activities, and source reduction activities over the calendar year for the chemical. These reports must reflect the releases and other waste management activities and source reduction activities across the entire facility.

For TRI reporting purposes, a "facility" includes all buildings, equipment, structures, and other stationary items that are located on a single site or on contiguous or adjacent sites and that are owned or operated by the same person (*e.g.*, individual, company, corporation, trust, firm) or by any person that controls, is controlled by, or under common control with, such person. EPCRA §

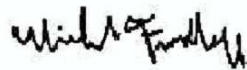
329(4), (7); 40 C.F.R. § 372.3. A facility may contain or be comprised of multiple establishments (*i.e.*, distinct and separate economic units) located on a single site or on contiguous or adjacent sites. 40 C.F.R. § 372.3. This determination is not intended to limit the scope of any TRI reporting that may be required from the facility listed above to only a portion of the whole TRI facility. Therefore, any facility covered under the reporting requirements of EPCRA Section 313(a) must consider chemical activities from the entire facility (including all establishments and other stationary structures) when determining whether chemical reporting thresholds have been met.

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. Each day a facility fails to meet any of the requirements constitutes a separate violation of the specific requirement. Submission of false information to EPA or knowing failure to file an EPCRA Section 313 report may also be subject to criminal penalties under Title 18, Section 1001.

EPA provides online TRI reporting guidance through TRI GuideME, www.epa.gov/tri/guideme. Such guidance includes the annual TRI Reporting Forms and Instructions covering TRI reporting criteria, reporting requirements, and how to submit any required reporting forms. GuideME also includes reporting Q&As, training modules, and guidance documents.

If you have questions about this determination or its requirements, please contact Stephanie Griffin (griffin.stephanie@epa.gov). If you have general questions on TRI reporting, please contact tri.help@epa.gov.

Sincerely,



Michal Freedhoff
Assistant Administrator

Attachment

cc: Regional TRI Coordinators (via email)