

ACCIDENTAL AMPOULE ACTIVATION

OUTSIDE STERILIZER

DOES NOT POSE IMMEDIATE DANGER

This study¹ examines the risks of accidental activation of the Anprolene® ampoule outside of the sterilization liner bag and sterilization cabinet. Specifically, how long it would take the ethylene oxide (EO) gas in the Anprolene gas release bag to diffuse into the room after accidental activation. This is a worst-case scenario, with the objective to measure EO levels that could only occur in the case of an accident or gross misuse of the Anprolene system. Under these conditions, results indicate that operators have at least 11 minutes to dispose of an activated gas release bag before EO levels reach OSHA short-term exposure limits.

MATERIALS:

1 AN71 (4.5ml) Anprolene® Ampoule
Shimadzu gas chromatograph and analyzer
1.0ml gas-tight syringes for gas collection

CONDITIONS:

The ambient room environment was measured at 68 to 70°F with relative humidity at approximately 45%.

The test room itself had no air changes. Performing the test in an unventilated room increases the risks associated with a malfunction of this kind. Andersen Products, Inc. recommends that the sterilizer be installed in a room with at least 10 air changes per hour. Operation of the sterilizer in a room with no air changes constitutes a gross misuse of the system.

METHODOLOGY AND EQUIPMENT:

The study was conducted to establish how long it would take the ethylene oxide gas in the Anprolene gas release bag to leak into the room after ampoule activation. This might represent the scenario of the gas release bag accidentally being dropped on the floor outside the sterilization cabinet, and the ampoule breaking. **The test is of an extreme condition, and one that is unlikely to occur. It is extremely unlikely that anyone would remain so close to the activated ampoule (a mere 1.5 feet) without taking any action.**

For the study, one 4.5ml ampoule was activated (broken) and placed on a tabletop. Samples of air were collected using a 1.0ml gas-tight syringe at approximately **18 inches (45.4 cm) from the activated ampoule**. Samples were taken until a trend could be established

and gas concentration was at the OSHA short-term exposure level limit.

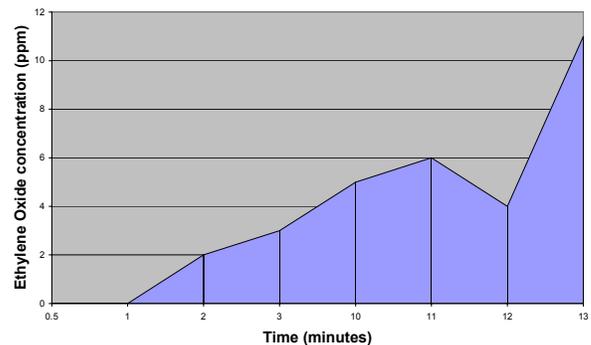
A gas chromatograph (GC) was used to test the concentration of ethylene oxide in the air samples.

RESULTS:

Time it took to reach OSHA STEL limit for EO levels

	OSHA allowable limit	Amount of time to reach limit
Test 1102 (gas diffusion after accidental ampoule activation)	5ppm	11 < 13 minutes

Ethylene Oxide Concentration Diffusing Through Gas Release Bag After Accidental Activation



CONCLUSION:

It took 11 minutes after the activation of the gas ampoule for the gas concentration level, measured at a very close distance, to reach the OSHA short-term exposure level limit. We can conclude that there is no immediate danger to an operator should there be an accidental activation of a gas ampoule.

¹ The test, AN74i AmpExp 1102, was conducted by Andersen Scientific, Inc. For more information on this test, please e-mail ansci@mindspring.com.