# Study of the influence of ethylene oxide sterilization variables on Bacillus subtilis inactivation

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## Introduction

Nowadays, ethylene oxide (EO) is a dominant sterilization agent used in medical device industry due to its effectiveness and compatibility with most materials, together with the technical and technological advances that allow overlapping difficulties associated to this agent.

## Aim

This work intends to study the influence of the process variables, e.g., temperature (T), ethylene oxide (EO) concentration and relative humidity (RH), on *Bacillus subtilis* inactivation, aiming to provide a predictive model of integrating lethality.

## Material and Methods

Experiments were carried out in an EO sterilizer with controlled temperature, EO concentration and humidity. The sporicidal activity of a specific EO sterilization cycle was assessed by recover and enumeration of bacterial viable spores from *B. subtilis* biological indicators.

## Results

Results showed that temperature and EO concentration were the most significant factors affecting the inactivation kinetics of *Bacillus subtilis*. Mathematical relations describing the influence of the referred process variables on microbial inactivation kinetics were successfully developed and achieved the final inactivation kinetic model:

$$\log\left(\frac{N}{N_0}\right) = (-7.5)\exp\left\{-\exp\left[\frac{-\left[\left(1.42\times10^{-4}T - 4.96\times10^{-3}\right) + \left(5.54\times10^{-8}T - 1.25\times10^{-6}\right)[EO]\right]e}{-7.5}\times\right.\right.$$

$$\left.\left.\times\left[\left(1.63\times10T - 1.06\times10^{3}\right)\ln([EO]) + \left(-1.25\times10^{2} + 8.23\times10^{3}\right) - t\right] + 1\right]\right\}$$

where N is the microbial load at a particular process time t (the index 0 is related to initial microbial load).

## Conclusion

An inactivation model that described the process kinetics only in terms of the relevant process variables (temperature and EO concentration) was achieved. The predictive ability of this integrated model was assessed, and its adequacy in predicting *B. subtilis* inactivation was verified.

The results of this work are certainly a contribution for an efficient control, design and optimization of the EO sterilization process.

**Keywords** Modelling, *Bacillus subtilis*, ethylene oxide, sterilization