

## Labelling Standard: Ethylene Oxide Gaseous Products Used in Sterilization Processes

### I. Description:

This labelling standard applies to ethylene oxide products labelled for use as gaseous sporicides in sterilizing medical instruments/devices. It does not apply to any other liquid and gaseous drug products to be used in sterilizing procedures and equipments for medical instruments/devices.

### II. Pharmaceutical Quality:

a. All ingredients (medicinal and nonmedicinal) and finished product should, as a minimum, meet the specifications described in the publications referred to in Schedule B to the *Food and Drugs Act* or equivalent standards. In the absence of a Schedule B standard, testing should be adequate to demonstrate the product's identity, potency, purity and quality.

#### b. Special Notes:

- i. Validation of sterilization and sterility assurance should be conducted according to the specifications in The United States Pharmacopoeia, USP 23, NF 18, Chapter <1211>.
- ii. The validation process should involve biological indicators prepared as detailed in The United States Pharmacopoeia, USP 23, NF 18, pages 202-204 and Chapter <1035>.

### III. Ingredients:

#### a. Single Medicinal Ingredient:

Ethylene oxide 10-100%

#### b. Nonmedicinal Ingredients:

Nonmedicinal ingredients should be restricted to the substances that are necessary for the formulation. Their concentration should not exceed the minimum required to provide their intended effect. Their presence should not adversely affect the efficacy or safety of the ethylene oxide and they should not interfere with assays and tests for the medicinal ingredients.

### IV. Labelling:

- a. This labelling standard describes the requirements that are specific for this type of product. Other requirements described in the *Food and Drugs Act* and *Regulations* should also be met.

b. **Unacceptable Claims:**

Statements such as non-toxic, non-irritant, safe, non-caustic, harmless, etc., are not considered appropriate for this type of product.

c. **Indications:**

For all products the labelling should indicate:

- i. For use in a sterilizer (model and type should be indicated) for medical instruments/devices in a health care facility (e.g, hospitals, dental clinic, etc.).

d. **Directions for Use**

- i. For all products complete directions for use as a gaseous disinfectant in a sterilizer **should be specified**, including:
- types of instruments (e.g, implants, surgical instruments, laparoscopes, burs, needles, etc.);
  - adequate wrapping procedures;
  - adequate load procedures;
  - specific precleaning procedures;
  - specific instructions for the safe and effective use of the product including specific cycle times, temperature, humidity, pressure of the ethylene oxide in the exposure chamber, adequate ventilation/aeration procedures, etc.
  - adequate in-process validation procedure (i.e., use of biological indicators) as indicated in Section II) b) ii).
- ii. A reference to an operator manual is considered acceptable provided that all the information listed in Section IV) d) i) is adequately addressed in the manual.
- iii. **Warnings:**

**For all products, the label should indicate the following symbols and statements:**

- the warning statement DANGER associated with the appropriate symbol
- the hazard symbol, signal word and hazard statements for pressurized containers as described in Sections A.01.060.1 to A.01.062 of the *Food and Drug Regulations*
- ETHYLENE OXIDE VAPOUR IS HARMFUL
- Avoid breathing vapours
- Keep container closed



- May cause burns
- Avoid contact with skin or eyes
- This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical use areas.
- First aid and toxicological information:

**For all products, the labelling should indicate the following statements:**

- In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes;
- For contact with eyes, call a physician;
- Remove and wash contaminated clothing before reuse;
- If ethylene oxide was swallowed, drink egg whites, gelatin solution or, if these are not available, drink large quantities of water. Call a physician.