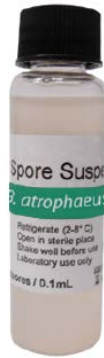




TERRAGENE



## Product name

**BT10S/2** – Spore suspension for direct inoculation of products or preparation of customized biological indicators for monitoring Ethylene Oxide and Dry Heat Sterilization Processes.

## Use

For monitoring Ethylene Oxide (EO) and Dry Heat Sterilization Processes.

## Applicable regulations

EN ISO 11138-1:2007 and EN ISO 11138-2:2009, EN ISO 11138-4:2007; IRAM 37102-1:1999 and IRAM 37102-2:1999.

## Classification

Class 1, according to risk.

## Authorization

Designed under Quality Systems ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM-1614-1.

## Product characteristics

Glass bottle: 18 mm diameter, 0.3 mm thick wall, 60.7 mm high.

Plastic cap: 16 mm external diameter, 9.4 mm high.

*Bacillus atrophaeus* ATCC 9372 spores.

Population:  $10^1$  spores/0.1 ml. Prepared in 40% ethanol.

Parameters specified:

D-Value<sub>EO</sub> is provided. Conditions: 600 mg/l EO, 60% RH, 54 °C.

D-Value<sub>DRY</sub> is provided. Calculated at 160 °C. Another D-value is estimated at 170 °C for the calculation of Z-Value<sub>DRY</sub>.

Z-Value<sub>DRY</sub> is provided.

Upon completion of the sterilization cycle, the inoculated product should be tested in a suitable culture medium at 37 °C. We suggest the use of culture media BIONOVA® MC1020 or MC1030 to final reading in 48 hours. For conventional culture media like TSB, incubation for 7 days at 37 °C is recommended.

## Environmental conditions during manufacture

Refrigeration during inoculation. Sterility conditions are necessary only during the filling and sealing process, carried out under laminar flow conditions.

## Storage conditions

For short-term use, store at 2-8 °C in refrigerator. Freeze to store for long periods (-10 to -25 °C). RH: 35-60 %. Keep out of direct light.

## Transportation conditions

Storage conditions should be strictly followed.

Transport in closed reinforced boxes to avoid damage. This product does not represent a risk for health. Bottles can be stored at temperature below 30 °C for up to 15 days during transportation.

## Shelf life

24 months.

## Packing

1 bottle with 10 ml of spore suspension within a plastic bag.

## Labelling

On the bottle: Product code and description, presentation and spore concentration, directions for use, batch number, manufacture and expiration date and manufacturer information.

## Possible target markets

Healthcare and Industry.

## Other important information (optional)

It is recommended to incubate at 37 °C in BIONOVA® IC10/20 incubator.

Read product's directions for use thoroughly before use.

**Note:** When necessary, limits for each product's parameters should be specified.



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**Description of identified and/or predictable risks and situations which could represent a risk for the product.**

Do not store the product near sterilizing agents.

Do not expose this product to Steam, H<sub>2</sub>O<sub>2</sub>, Radiation or any sterilization process other than EO and/or Dry Heat.

The positive biological indicator can be sterilized in gravity air displacement steam sterilizers at 121°C for at least 20 minutes or at 132 °C for at least 15 minutes, or at 134 °C for at least 10 minutes in vacuum-assisted steam sterilizers.

Note: Spores can be incubated in culture media BIONOVA® MC1030 or MC1020 culture media or other culture medium made up of soybean casein and yeast extract.