



HOJA DE DATOS DE SEGURIDAD DE PRODUCTOS (PRODUCT SAFETY DATA SHEET)

**PRODUCT: SELF-CONTAINED BIOLOGICAL INDICATOR
BIONOVA® TERRAGENE®**

Manufacturer: Terragene S.R.L.

1. PRODUCT DATA

Name: Self-contained Biological Indicator.

Code: BT10, BT20, BT30

Description: Designed for monitoring EO, Steam and Dry Heat sterilization processes respectively.

Formula: N/A

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Tube and plastic cap with hermetic closing containing *Bacillus atrophaeus* ATCC 9372 (BT10 and BT30) / *Geobacillus stearothermophilus* ATCC 7953 (BT20) non-pathogenic bacterial spores soaked in a strip of paper, and growth indicating medium inside glass ampoule.

Population: 1-5 x 10⁶ CFU / unit, *Bacillus atrophaeus*. 1-5 x 10⁵ CFU / unit o 1-5 x 10⁶ CFU / unit, *Geobacillus stearothermophilus*.

Time of final reading: 24 - 48 hours.

3. HAZARD DATA

HAZARDOUS INGREDIENTS:

Paints, Preservatives, & Solvents: N/A

Alloys and Metallic coatings: N/A

Hazardous Mixtures of other liquids, solids, or gases: N/A

HEALTH HAZARD DATA

Eye Contact: No irritation is expected form accidental contact with microorganisms.

Skin Contact: No skin irritation is expected from accidental contact with the microorganisms.

Inhalation: Inhalation is not a likely route of exposure to this product. No health hazards are expected from accidental inhalation of the microorganisms.

If Swallowed: Ingestion is not a likely route of exposure to this product. No health hazards have been associated with accidental exposure to the microorganisms.

Other Health Hazard Information: The microorganisms contained on the biological indicators are non-pathogenic organisms.

Protective Clothing: The use of gloves, moisture impervious aprons, and other protective clothing must be dictated by the standard operational procedures of each individual laboratory. Wash hands thoroughly after handling.

This product contains no hazardous material. It does not present any risk on user's health. The biological material of which it is composed does not present any risk for the user's health



4. FIRST AID MEASURES

N/A

5. FIRE FIGHTING MEASURES

Flash Point: N/A

Flammable Limits: N/A

Fire and ignition: The product is composed of materials with low ignition rate.

6. ACCIDENTAL RELEASE MEASURES SPILL CLEAN-UP PROCEDURES

Steps to be taken in case material is spilled or released: Clean and disinfect exposed surface

7. HANDLING AND STORAGE

Store in dark place.

Temperatures: 15 – 30 °C

Relative humidity: 35 – 60 %

Do not freeze

Do not store near sterilizing agents or other chemical products.

8. OCCUPATIONAL EXPOSURE LIMITS

N/A

9. EXPOSURE CONTROL / PERSONAL PROTECTION

N/A

10. PHYSICAL DATA

Boiling Point: N/A

Vapor Pressure: N/A

Vapor Density: N/A

Solubility in Water: Negligible

Specific Gravity: N/A

Evaporation Rate: N/A

Appearance and Odor: This product contains microorganisms inoculated on a paper filter disc and a glass ampoule packaged in a covered plastic tube. There is no specific odor associated with this product.

11. STABILITY AND REACTIVITY

Stability: The product is stable if the proper storage conditions are met.

Reactivity: N/A

Incompatibility: N/A

Hazardous Decomposition Products: N/A

Hazardous Polymerization: N/A



12. DISPOSAL CONSIDERATIONS:

Waste Disposal Method:

For product disposal it is recommended to sterilize it in autoclave at 121° C for at least 15 minutes, in gravity displacement steam sterilizer at 132° C for at least 10 minutes, or in vacuum steam sterilizer at 132° C for at least 4 minutes.

Do not re-use the product.

13. TRANSPORT INFORMATION

This product does not present any risk on eventual accidents which may happen during shipping.

14. REGULATORY INFORMATION

N/A

OTHER INFORMATION:

Biological Indicators TERRAGENE® BIONOVA® are not hazardous products.

Biological Indicators TERRAGENE® BIONOVA® do not have any specifications for transportation and they are not potential risks for the environment or for human beings.