Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

1.1. Product Identifier

Product form: Mixture.

Trade name: ProEdge SM-BIOIN Biological Indicator.

1.2. Relevant identified uses of the substance or mixture and uses against

1.2.1. Relevant identified uses of the substance or mixture:

ProEdge SM-BIOIN Biological Indicator is designed for monitoring vacuum assisted and gravity air-displacement steam sterilization processes.

1.2.2. Uses advised against:

Do not use for purposes other than stated in the indications for use.

1.3. Details of the supplier of the safety sheet

Manufacturer: Terragene S.A.

Address: Ruta Nacional Nº 9, Km 280 - CP 2130 - Parque Industrial Micropi - Alvear - Santa Fe - Argentina

Produced by: QA&RA Department

Info Telephone: +54 341 5587007 | 5587008 | 5587009

E-mail: info@terragene.com

Web Page: www.terragene.com

1.4. Emergency telephone

Emergency Number: (+54 341) 558-7007. 8:00 AM – 5:00 PM (GMT-3).

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008 (CLP).

CLASSIFICATION:
N/A

Adverse physicochemical, human health and environmental effects:

No information available.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 (CLP).

2.2.1. Hazard pictograms

N/A

2.2.2 Signal word

N/A

2.2.3. Hazard statements

N/A

2.2.4. Precautionary statements

N/A

2.2.5. Supplemental Hazard information (EU):

N/A.

2.3. Other hazards

The microorganisms contained in ProEdge SM-BIOIN Biological Indicator are non-pathogenic organisms.

PBT: not yet assessed.

VPvB: not yet assessed.

Section 3: COMPOSITION/ INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable.

3.2. Mixture

Substances presenting a health or environmental hazard within the meaning of the Dangerous Substances Regulation (EC) No. 1272/2008 (CLP).

ProEdge SM-BIOIN Biological Indicator consists of a plastic tube and lid with hermetic seal containing non-pathogenic spores of *Geobacillus stearothermophilus* ATCC®* 7953 embedded in carriers, and indicator culture medium contained within a glass ampoule.

Ingredients	CAS Number	Content %	EC Number	Classification according to Regulation (EC) No. 1272/2008 (CLP)
Vial	N/A	40-50	N/A	N/A
Cap	N/A	20-25	N/A	N/A
Ampoule	N/A	10-20	N/A	N/A
Culture media	N/A	10-15	N/A	N/A
Spores of *G. stearothermophilus*	N/A	<0,05	N/A	N/A

Comments: Exact concentrations are withheld as trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

4.1.1. General:

No need for first aid is anticipated.

4.1.2. In case of ingestion:

No need for first aid is anticipated.

4.1.3. In case of eye contact:

No need for first aid is anticipated.

4.1.4. In case of skin contact:

No need for first aid is anticipated.

4.1.5. In case of inhalation:

No need for first aid is anticipated.

4.2. Most important symptoms and effects, both acute and delayed

N/A

4.3. Indication of any immediate medical attention and special treatment needed

N/A

Section 5: FIREFIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water, foam, carbon dioxide (CO2) or dry chemical powder.

Unsuitable extinguishing media: None known.

5.2. Special hazards arising from the substance or mixture

N/A

5.3. Advice for firefighter

N/A

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

N/A

6.1.1. For non-emergency personnel

N/A

6.1.2. For emergency responders

N/A

6.2. Environmental precautions

N/A

6.3. Methods for containment and cleaning up

Methods for cleaning up: Comply with applicable local and national regulations. Spills may be picked up with a mop and followed by a water rinse. Residue may be washed down with water. Smalls spills may be flushed to a sanitary sewer with copious amounts of water, if in accordance with local, state or national legislation.

Released material in dry form may be swept up using a broom and dust pan or picked up by hand if wearing protective gloves. Clean up residue. Seal container. Dispose of collected material according to country´s healthcare and safety regulations.

6.4. Reference to other sections

Section 8 and 13.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautionary for safe handling: Read label before use. ProEdge SM-BIOIN Biological Indicators are designed to be used in different steam sterilizers. When used in such devices, no inherent hazards are likely to present themselves. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation.

Hygiene measures: Take care for general good hygiene and housekeeping. Do not drink, eat, smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in dark, dry conditions before and after use. Do not freeze. Ensure adequate ventilation. Avoid dust formation.

Incompatible materials: Do not store near sterilizing agents or other chemical products.

Keep away from sources of ignition.

Temperatures: 10 – 30 °C.

Relative humidity: 30 – 80 %.

7.3. Specific end use(s)

ProEdge SM-BIOIN Biological Indicators are designed for monitoring vacuum assisted and gravity air-displacement steam sterilization processes.

Section 8: EXPOSURE CONTROL / PERSONAL PROTECTION

8.1. Control parameters

8.1.1. Occupational Exposure Limits

Exposure limits

This product, as supplied, does not contain any hazardous material with occupational exposure limits established by the region specific regulatory bodies.

8.2. Exposure controls

8.2.1. Engineering controls

No engineering controls are necessary.

8.2.2. Personal protective equipment

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.

Hand protection: According to operational procedures of each individual laboratory.

Eye protection: According to operational procedures of each individual laboratory.

Skin and body protection: According to operational procedures of each individual laboratory.

Respiratory protection: According to operational procedures of each individual laboratory.

8.2.3. Environmental exposure controls

N/A

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State:	Varies
Appearance:	Varies
Color:	Varies
Odour:	N/A
Odour threshold:	N/A
pH:	N/A
Relative evaporation rate:	N/A
Melting point/Freezing point:	N/A
Boiling point:	N/A
Flash point:	N/A
Flammability:	N/A
Vapour pressure:	N/A
Relative vapour density at 20 °C:	N/A
Relative density:	N/A
Log Pow:	N/A
Explosive properties:	N/A
Oxidising properties:	N/A
Solids:	N/A
Viscosity:	N/A
Decomposition Temp.:	N/A
Explosive Limits:	N/A
Auto-ignition Temp.:	N/A
Solubility:	N/A

9.2. Other information

VOC's (ASTM D 2369-87): N/A

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Stable under recommended storage conditions (see section 7).

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

Hazardous decomposition products: N/A.

Hazardous polymerization: N/A.

10.4. Conditions to avoid

Avoid excessive heat and pressure. Avoid dust formation.

10.5. Incompatible materials

Sterilizing agents.

10.6. Hazardous decomposition products

None under normal conditions of use.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Signs and symptoms of exposure

Acute toxicity: Not available. Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Not available. Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Not available. Based on available data, the classification criteria are not met.

Respiratory or skin sensitization: Not available. Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Not available. Based on available data, the classification criteria are not met.

Carcinogenicity: Not available. Based on available data, the classification criteria are not met.

Reproductive toxicity: Not available. Based on available data, the classification criteria are not met.

Specific target organ toxicity (single exposure): Not classified. Based on available data, the classification criteria are not met.

Aspiration hazard: Not classified. Based on available data, the classification criteria are not met.

Additional Information: This product, when used under appropriate conditions and in accordance with the instructions for use, should not present any risk to health. However, the use or processing of the product in a manner not covered by the product instructions could affect the operation of the product and present a potential risk to health and safety.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects.

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose in a safe manner in accordance with federal, state provincial and local regulations.

For product disposal it is recommended to autoclave positive biological indicators in a gravity air displacement steam sterilizer at 121 °C for 30 minutes, 132 °C for 15 minutes or 134 °C for 10 minutes; or in a dynamic air removal steam sterilizer at 132 °C for 4 minutes or 135 °C for 3 minutes.

Avoid release to the environment.

Section 14: TRANSPORT INFORMATION

14.1. UN number

Not considered a dangerous good according to IATA, IMDG, ADN, ADR, RID Dangerous Goods Regulations.

14.2. UN proper shipping name

N/A

14.3. Transport hazard class (es)

N/A

14.4. Packing group

N/A

14.5. Environmental hazards

N/A

14.6. Special precaution for users

No additional information available.

14.7. Transport in bulk according to Annex II MARPOL 73/78 and the IBC CODE

N/A

Section 15: REGULATORY INFORMATION

15.1. Safety, Health and environmental regulation/legislation specific for the substance or mixture

Contains no REACH Annex XIV substances.

Contains no REACH substances with Annex XVII restrictions.

Contains no substance on the REACH Candidate List.

15.2. Chemical safety assessment

No chemical safety assessment is required.

Section 16: OTHER INFORMATION

According to Regulation (EU) 2015/830.

Indication of changes: N/A

Abbreviations and acronyms:

CLP: Classification, Labelling and Packaging.

CAS number: Chemical Abstracts Service number.

Data sources:

https://echa.europa.eu/information-on-chemicals/cl-inventory-database

https://echa.europa.eu/es/information-on-chemicals

Regulation on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

16.1. Legal disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The company shall not be held liable for any damage resulting from handling or from contact with the above product.

16.2. Date of issue/Date of revision

29-12-2025

16.3. Revision number

02

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