

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING**1.1. Product Identifier**

Product form: mixture

Trade name: Bionova® IC10/20 Incubator; Bionova® IC10/20FR and Bionova® IC10/20FRLCD Auto-reader Incubators; Bionova® MiniBio Auto-reader Incubator; Bionova® MiniPro Auto-reader Incubator; Bionova® Photon BPH Auto-reader Incubator; Bionova® Hyper BHY Auto-reader Incubator; Bionova® TB-IC1020 Thermometer for Bionova® Incubators; Bionova® ICTP and ICTP Mini Incubator thermal papers.

1.2. Relevant identified uses of the substance or mixture and uses against**1.2.1. Relevant identified uses of the substance or mixture:**

Bionova® IC10/20 for incubation and readout of: Bionova® Biological Indicators: BT10 (steam) 48 h at 37 °C, BT20 (steam) 24 h at 60 °C, BT30 (dry heat) 48 h at 37 °C, BT91 (VH₂O₂) 24 h at 60 °C and BT100 (formaldehyde) 48 h at 60 °C and Bionova® Self-contained spore ampoules: BT21 (steam) 48 h at 60 °C, BT22 (steam) 48 h at 60 °C, BT23 (steam) 48 h at 60 °C, BT24 (steam) 48 h at 37 °C and BT31 (dry heat) 72 h at 37 °C.

Bionova® IC10/20FR and Bionova® IC10/20FRLCD for incubation and readout of: Bionova® Rapid Fluorescence Readout BI: BT220 (steam) 3 h at 60 °C, BT110 (EO) 4 h at 37 °C, BT102 (formaldehyde) 2 h at 60 °C and BT95 (VH₂O₂) 2 h at 60 °C; Bionova® Super Rapid Fluorescence Readout BI: BT222 (steam) 1 h at 60 °C and BT96 (VH₂O₂) 30 min. at 60 °C; and Bionova® Ultra Rapid Fluorescence Readout BI: BT224 (steam) 20 min. at 60 °C and Chemdye® Protein Pen 7 min at 60 °C.

Bionova® MiniBio for incubation and readout of: Bionova® Rapid Fluorescence Readout BI: BT220 (steam) 3 h at 60 °C, BT110 (EO) 4 h at 37 °C, BT102 (formaldehyde) 2 h at 60 °C and BT95 (VH₂O₂) 2 h at 60 °C; Bionova® Super Rapid Fluorescence Readout BI: BT222 (steam) 1 h at 60 °C and BT96 (VH₂O₂) 30 min. at 60 °C; and Bionova® Ultra Rapid Fluorescence Readout BI: BT224 (steam) 20 min. at 60 °C.

Bionova® MiniPro for incubation and quantitative readout of: Pen system for the detection of surface proteins and allergens Chemdye® PRO1 MICRO 4 min. at 60 °C.

Bionova® Photon BPH for incubation and readout of Bionova® Photon Self-contained Biological Indicator (BT225);

Bionova® Hyper BHY for incubation and readout of Bionova® Hyper Self-contained Biological Indicator BT98 (VH₂O₂) 5min. at 60 °C;

Bionova® TB-IC1020 accessory for temperature monitoring for Bionova® Incubators;

Bionova® ICTP and ICTP Mini for incubator printing;

1.2.2. Uses advised against:

Do not use for purposes other than manufacturer's indicated.

1.3. Details of the supplier of the safety sheet

Manufacturer: Terragene S.A.

Address: Ruta Nacional N° 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).

The product is not classified as hazardous according to OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

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).

Ingredients	CAS Number	Content %	EC Number	Classification according to Regulation (EC) No. 1272/2008 (CLP)
Non-hazardous components	N/A	100	N/A	N/A

Section 4: FIRST AID MEASURES**4.1. Description of first aid measures****4.1.1. General:**

N/A

4.1.2. In case of ingestion:

N/A

4.1.3. In case of eye contact:

N/A

4.1.4. In case of skin contact:

N/A

4.1.5. In case of inhalation:

N/A

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: Carbon dioxide (CO₂) or dry chemical powder.

Unsuitable extinguishing media: Water, foam.

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

N/A

6.4. Reference to other sections

N/A

Section 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Precautionary for safe handling: Do not handle until all safety precautions have been read and understood.

Hygiene measures: Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: store in dark, dry conditions.

Keep away from sources of ignition.

Temperature: 5 - 40 °C

Relative humidity: 30 - 80 %

7.3. Specific end use(s)

Bionova® IC10/20 for incubation of Biological Indicators and Hygiene Monitoring Systems; Bionova® IC10/20FR and Bionova® IC10/20FRLCD for incubation and readout of Rapid, Super Rapid or Ultra Rapid Biological Indicators and Hygiene Monitoring Systems; Bionova® MiniBio for incubation and readout of Rapid, Super Rapid or Ultra Rapid Biological Indicators; Bionova® MiniPro for Hygiene Monitoring Systems; Bionova® Photon BPH Auto-reader Incubator for incubation and automatic readout of Bionova® Photon Self-contained Biological Indicator (BT225); Bionova®

Hyper BHY Auto-reader Incubator for incubation and automatic readout of Bionova® Hyper Self-contained Biological Indicator (BT98); Bionova® TB-IC1020 accessory for temperature sensing for Bionova® Incubators; Bionova® ICTP and ICTP Mini for incubator printing.

Section 8: EXPOSURE CONTROL / PERSONAL PROTECTION

8.1. Control parameters

8.1.1. Occupational Exposure Limits

N/A

8.2. Exposure controls

8.2.1. Engineering controls

N/A

8.2.2. Personal protective equipment

None required.

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:	Solid
Appearance:	N/A
Color:	N/A
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 (for Cup n° 6):	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.

10.3. Possibility of hazardous reactions

Hazardous Decomposition Products: N/A.

Hazardous Polymerization: N/A

10.4. Conditions to avoid

None in particular.

10.5. Incompatible materials

Information not available.

10.6. Hazardous decomposition products

N/A

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Signs and symptoms of exposure

Acute toxicity: Not available.

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory or skin sensitization: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Specific target organ toxicity (single exposure): Not available.

Specific target organ toxicity (repeated exposure): Not available.

Aspiration hazard: Not available.

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 accordance with all federal, state provincial and local regulations.

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, Labeling 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, labeling 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

15-10-2024

16.3. Revision number

05