



## SAFETY DATA SHEET

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

**1.1. Product identifier:**

**NG-Test CTX-M MULTI**

Ref. NGB-CTM-S23-XXX

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

Rapid and qualitative immunoassay for the detection of ESBL CTX-M enzyme from groups 1, 2, 8, 9 and 25 in bacterial colony from culture. In vitro diagnostic for professional use.

**1.3. Details of the supplier of the safety data sheet:**

Information about the user:

**NG Biotech**

Atelier relais le Tremplin. Parc d'act. de Courbouton, Sect. 1  
Guipry 35480 Guipry-Messac  
France  
Tel: +33 (0)2 23 30 17 83

1.3.1. Responsible person: Jean-Baptiste BAUDIER  
E-mail: [jb.baudier@ngbiotech.com](mailto:jb.baudier@ngbiotech.com)

**1.4. Emergency telephone number:** +33 (0) 2 23 30 17 83

### SECTION 2: HAZARDS IDENTIFICATION

**2.1. Classification of the substance or mixture:**

Classification according to Regulation (EC) No 1272/2008 (CLP):

**Not considered as hazardous mixture.**

**Hazard statements:** No hazard statements.

**2.2. Label elements:**

**Hazard statements:** No hazard statements.

**Precautionary statements:** No precautionary statements.

**2.3. Other hazards:**

The product has no other known specific hazards for human or environment.

Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.

Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substances:**

Not applicable.

**3.2. Mixtures:**

Description: The kit is composed by a test strip (sample pad, nitrocellulose membrane pre-coated with antibodies, polyester release matrix pre-coated with antibodies labelled with colloidal gold and absorbent pad) protected by a plastic housing, one vial of extraction buffer and accessories.

Mixture including substances found in traces listed below, with non-hazardous additions.

Description	CAS number	EC number / ECHA list number	REACH registration number	Conc. (%)	Classification according to Regulation (EC) No 1272/2008 (CLP)		
					Pictogram, signal word code(s)	Hazard class and category code(s)	Hazard statement code(s)
<b>Ethylenediamine-tetraacetic acid disodium salt dihydrate**</b>	6381-92-6	205-358-3	01-2119486775-20	<0.1	GHS07 GHS08 Warning	Acute Tox. 4 STOT RE 2 Aquatic Chronic 3	H332 H373 H412
<b>N,N-dimethylformamide***</b> Index number: 616-001-00-X	68-12-2	200-679-5	-	<0.1	GHS08 GHS07 Danger	Repr. 1B Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2	H360D H332 H312 H319
<b>Sodium azide*/***</b> Index number: 011-004-00-7	26628-22-8	247-852-1	01-2119457019-37	<0.1	GHS06 GHS08 GHS09 Danger	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H300 H330 H310 H373 (brain) H400 H410 EUH032

\*: Classification specified by the manufacturer that includes other classification in addition to the classification specified by Regulation (EC) No 1272/2008.

\*\* : Classification specified by the manufacturer; the substance is not listed in Annex VI of the Regulation (EC) No 1272/2008.

\*\*\*: Substance having occupational exposure limit value.

For the full text of hazard statements, see Section 16.

### SECTION 4: FIRST AID MEASURES

**4.1. Description of first aid measures:**

**General information:** The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the strip.

**INGESTION:**

Measures:

- Rinse mouth with water.

**INHALATION:**

Measures:

- Remove the person from the contaminated area.

**SKIN CONTACT:**

Measures:

- Wash with soap and plenty of water.

**EYE CONTACT:**

Measures:

- Rinse eyes with water as a precaution.

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

No acute and delayed symptoms and effects known.

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



No special treatment

needed; treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

- 5.1. **Extinguishing media:**
  - 5.1.1. **Suitable extinguishing media:**  
Water fog, foam, dry chemical, carbon dioxide.  
Choose extinguishing media depending on surrounding fire.
  - 5.1.2. **Unsuitable extinguishing media:**  
No data available.
- 5.2. **Special hazards arising from the substance or mixture:**  
The device is not flammable.  
No special hazards known.
- 5.3. **Advice for firefighters:**  
Wear full protective clothing and self-contained breathing apparatus.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

Information are pertinent only with an abusive use of the device (opening the device with a direct exposition of chemical products).

- 6.1. **Personal precautions, protective equipment and emergency procedures:**
  - 6.1.1. **For non-emergency personnel:**  
Allow only well-trained experts wearing suitable protective clothing to abide in the field of accident.
  - 6.1.2. **For emergency responders:**  
Avoid direct contact with skin, eyes, mucous membranes, and clothing with appropriate personal protective equipment (PPE) including gloves and lab coat.
- 6.2. **Environmental precautions:**  
Avoid release in the environment.
- 6.3. **Methods and material for containment and cleaning up:**  
Dispose of in a biological and risk of infection bin.
- 6.4. **Reference to other sections:**  
For further and detailed information see Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

- 7.1. **Precautions for safe handling:**  
Observe conventional hygiene precautions.  
Do not eat, drink or smoke in the zone of manipulation.  
**Technical measures:**  
Wearing individual protective equipment is recommended.  
**Precautions against fire and explosion:**  
No special measures required.
- 7.2. **Conditions for safe storage, including any incompatibilities:**  
**Technical measures and storage condition:**  
No special measures required.  
**Storage temperature:** 4 – 30 °C.  
**Incompatible materials:** See Section 10.5  
**Packaging material:** No special prescriptions.
- 7.3. **Specific end use(s):**  
See Section 1.2.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. **Control parameters:**

**Occupational exposure limit values** (Commission Directive (EC) No 2000/39 of 8 June 2000):

**Sodium azide** (CAS: 26628-22-8): 8 hours: 0.1 mg/m<sup>3</sup>; Short term: 0.3 mg/m<sup>3</sup> (Skin)

**N,N Dimethylformamide** (CAS: 68-12-2): 8 hours: 15 mg/m<sup>3</sup>, 5 ppm; Short term: 30 mg/m<sup>3</sup>, 10 ppm (Skin)

DNEL values		Oral exposure		Dermal exposure		Inhalative exposure	
		Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)
Consumer	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data
Worker	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data

PNEC values		
Compartment	Value	Note(s)
Freshwater	no data	no notes
Marine water	no data	no notes
Freshwater sediment	no data	no notes
Marine water sediment	no data	no notes
Sewage Treatment Plant (STP)	no data	no notes
Intermittent release	no data	no notes
Secondary poisoning	no data	no notes
Soil	no data	no notes

#### 8.2. **Exposure controls:**

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

##### 8.2.1. **Appropriate engineering controls:**

In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin.

##### 8.2.2. **Individual protection measures, such as personal protective equipment:**

1. **Eye/face protection:** Not required.
2. **Skin protection:**
  - a. **Hand protection:** Not required.
  - b. **Other:** Not required.
3. **Respiratory protection:** Not required.
4. **Thermal hazards:** No thermal hazards known.

##### 8.2.3. **Environmental exposure controls:**

No specific prescription.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions, an expert's advice is necessary before deciding upon further protective measures.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. **Information on basic physical and chemical properties:**

Parameter	Value / Test method / Remarks
1. Physical state	solid
2. Colour	white
3. Odour, odour threshold	no data*
4. Melting point/freezing point	no data*
5. Boiling point or initial boiling point and boiling range	no data*
6. Flammability	no data*
7. Lower and upper explosion limit	no data*
8. Flash point	no data*
9. Auto-ignition temperature	no data*
10. Decomposition temperature	no data*
11. pH	no data*
12. Kinematic viscosity	no data*



13. Solubility in water in other solvents	no data* no data*
14. Partition coefficient n-octanol/water (log value)	no data*
15. Vapour pressure	no data*
16. Density and/or relative density	no data*
17. Relative vapour density	no data*
18. Particle characteristics	no data*

9.2. **Other information:**

9.2.1. **Information with regard to physical hazard classes:**

No further data available or not applicable for the product.

9.2.2. **Other safety characteristics:**

No other characteristics available.

\*: The manufacturer did not carry out any tests on this parameter for the product or the results of the tests are not available at the time of publication of the data sheet, or the property is not applicable for the product.

## SECTION 10: STABILITY AND REACTIVITY

10.1. **Reactivity:**

No dangerous reactions known if handled under normal conditions of use.

10.2. **Chemical stability:**

Stable under recommended storage temperature.

10.3. **Possibility of hazardous reactions:**

No hazardous reactions known if used for the intended purpose.

10.4. **Conditions to avoid:**

No conditions to avoid known if used for the intended purpose.

10.5. **Incompatible materials:**

No incompatible materials known.

10.6. **Hazardous decomposition products:**

No hazardous decomposition products known.

## SECTION 11: TOXICOLOGICAL INFORMATION

11.1. **Information on hazard classes as defined in Regulation (EC) No 1272/2008:**

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

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

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

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

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

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

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

**STOT-single exposure:** Based on available data, the classification criteria are not met.

**STOT-repeated exposure:** Based on available data, the classification criteria are not met.

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

11.1.1. **Summaries of the information derived from the test conducted:**

No data available.

11.1.2. **Relevant toxicological properties:**

No data available about the product.

Information about the components:

**Ethylenediamine-tetraacetic acid disodium salt dihydrate** (CAS: 6381-91-6):

Acute toxicity:

LD<sub>50</sub> (oral, rat, male and female): 2800 mg/kg (OECD 401)

ATE (inhalation): 1.6 mg/l (expert judgement)

Serious eye damage/eye irritation:

Eyes - Rabbit

Result: No eye irritation

Remarks: (ECHA) (anhydrous substance)

**Sodium azide** (CAS: 26628-22-8):



Acute toxicity:

LD<sub>50</sub> (oral, rat): 27 mg/kg

LC<sub>50</sub> (inhalation, rat, male and female): 0.054 – 0.52 mg/l/4 hours

LD<sub>50</sub> (dermal, rabbit) : 20 mg/kg

Skin corrosion/irritation:

Skin - In vitro study

Result: No skin irritation (OECD 439)

Serious eye damage/irritation:

Eyes - Bovine cornea

Result: No eye irritation - 4 h (OECD 437)

Respiratory or skin sensitisation:

Local lymph node assay (LLNA) - Mouse

Result: negative (OECD 429)

Germ cell mutagenicity:

Test Type: Mutagenicity (mammal cell test): chromosome aberration.

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

Test Type: unscheduled DNA synthesis assay

Test system: Chinese hamster lung cells

Metabolic activation: without metabolic activation

Method: OECD Test Guideline 482

Result: negative

Test Type: sister chromatid exchange assay

Test system: Chinese hamster ovary cells

Metabolic activation: without metabolic activation

Method: OECD Test Guideline 479

Result: negative

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Nausea, headache, vomiting. Laboratory experiments in animals have shown sodium azide to produce a profound hypotensive effect, demyelination of myelinated nerve fibers in the central nervous system, testicular damage, blindness, attacks of rigidity, and hepatic and cerebral effects., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**11.1.3. Information on likely routes of exposure:**

Ingestion, inhalation, skin contact, eye contact.

**11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:**

No data available.

**11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:**

Based on our experiences and the available information, in case of proper use and handling, no adverse effects on health can be expected.

**11.1.6. Interactive effects:**

No data available.

**11.1.7. Absence of specific data:**

No information.

**11.2. Information on other hazards:**

**Endocrine disrupting properties:**

Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

**Other information:**

Information are pertinent only with an abusive use of the device (opening the device with a direct exposition of chemical products).

## SECTION 12: ECOLOGICAL INFORMATION

Information are pertinent only with an abusive use of the device (opening the device with a direct exposition of chemical products).

**12.1. Toxicity:**



classified as hazardous for the

The mixture is not environment.

Information about the components:

**Sodium azide** (CAS: 26628-22-8):

LC<sub>50</sub> (Oncorhynchus mykiss): 2.75 mg/l/96 hours (OECD 203, flow-through)

ErC<sub>50</sub> (Pseudokirchneriella subcapitata): 0.35 mg/l/96 hours (OECD 201, static)

12.2. **Persistence and degradability:**

Information about the components:

**Sodium azide** (CAS: 26628-22-8):

The methods for determining biodegradability are not applicable to inorganic substances.

12.3. **Bioaccumulative potential:**

No data available.

12.4. **Mobility in soil:**

No data available.

12.5. **Results of PBT and vPvB assessment:**

Based on available data, the product does not contain any PBT or vPvB substances.

12.6. **Endocrine disrupting properties:**

Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

12.7. **Other adverse effects:**

No data available.

## SECTION 13: DISPOSAL CONSIDERATIONS

13.1. **Waste treatment methods:**

Disposal according to the local regulations.

13.1.1. **Information regarding the disposal of the product:**

Dispose the device and/or the packing of in a biological and risk of infection bin in compliance with national rules.

**List of Waste Code:**

No waste disposal key according to the List of Waste Code (LoW code) can be determined for this product, as only the purpose of application defined by the user enables an allocation. The LoW code number has to be determined after a discussion with a waste disposal specialist.

13.1.2. **Information regarding the disposal of the packaging:**

Dispose the device and/or the packing of in a biological and risk of infection bin in compliance with national rules.

13.1.3. **Physical/chemical properties that may affect waste treatment options shall be specified:**

No data available.

13.1.4. **Sewage disposal:**

No data available.

13.1.5. **Special precautions for any recommended waste treatment:**

No data available.

## SECTION 14: TRANSPORT INFORMATION

ADR/RID; ADN; IMDG; IATA:

Not subject to the conventions of carriage of dangerous goods.

14.1. **UN number or ID number:**

No UN or ID number.

14.2. **UN proper shipping name:**

No proper shipping name.

14.3. **Transport hazard class(es):**

No transport hazard classes.

14.4. **Packing group:**

No packing group.

14.5. **Environmental hazards:**

See Section 12.

14.6. **Special precautions for user:**

See Section 6.

14.7. **Maritime transport in bulk according to IMO instruments:**

Delivery will only be made in an approved and regulated packaging.

## SECTION 15: REGULATORY INFORMATION



**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:**

**REGULATION (EC) No 1907/2006** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive (EC) No 1999/45 and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive (EEC) No 76/769 and Commission Directives (EEC) No 91/155, (EEC) No 93/67, (EC) No 93/105 and (EC) No 2000/21

**REGULATION (EC) No 1272/2008** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives (EEC) No 67/548 and (EC) No 1999/45, and amending Regulation (EC) No 1907/2006

**COMMISSION REGULATION (EU) 2020/878** of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Does not contain substances in a quantity of more than 0.1 % which are included in the Candidate List for Authorisation of Substances of Very High Concern (SVHC) under Regulation (EC) No 1907/2006 (REACH).

The mixture contains a substance that is listed in Annex XVII of Regulation (EC) No 1907/2006 (REACH) and is therefore restricted:

**N,N-dimethylformamide** (CAS: 68-12-2)

Conditions of restriction: Item 76.

Conditions of restriction: Item 30.

**15.2. Chemical safety assessment:** The mixture has not been subject to a safety assessment.

## SECTION 16: OTHER INFORMATION

**Information regarding the revision of the safety data sheet:**

The safety data sheet has been revised according to Regulation (EU) 2020/878 (Section 1-16).

The composition of the mixture was modified compared to the previous version.

The hazard classification of the mixture did not change compared to the previous version.

This safety data sheet supersedes all previous versions according to Annex II of Regulation (EC) No 1907/2006.

**Literature references / data sources:**

Previous version of the safety data sheet (21. 10. 2019, version 2)

Information provided by the manufacturer (safety data sheets of the ingredients)

**Methods used for the classification according to Regulation (EC) No 1272/2008:**

Based on the calculation method carried out on the basis of the known hazards of the components, not considered as a hazardous mixture.

**Relevant hazard statements (code and full text) of Sections 2 and 3:**

**H300** – Fatal if swallowed.

**H310** – Fatal in contact with skin.

**H312** – Harmful in contact with skin.

**H319** – Causes serious eye irritation.

**H330** – Fatal if inhaled.

**H332** – Harmful if inhaled.

**H360D** – May damage the unborn child.





- H373** – May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
- H400** – Very toxic to aquatic life.
- H410** – Very toxic to aquatic life with long lasting effects.
- H412** – Harmful to aquatic life with long lasting effects.
- EUH 032** – Contact with acids liberates very toxic gas.

**Training advice:** No data available.

**Full text of the abbreviations in the safety data sheet:**

- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
- ADR: Agreement concerning the International Carriage of Dangerous Goods by Road.
- ATE: Acute Toxicity Estimate.
- AOX: Adsorbable organic halides.
- BCF: Bioconcentration factor.
- BOD: Biological Oxygen Demand.
- CAS number: Chemical Abstract Service number.
- CLP: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
- CMR effects: Carcinogenic, mutagenic, reprotoxic effects.
- COD: Chemical Oxygen Demand.
- CSA: Chemical Safety Assessment.
- CSR: Chemical Safety Report.
- DNEL: Derived-No-Effect-Level.
- ECHA: European Chemical Agency.
- EC: European Community.
- EC number: EINECS and ELINCS numbers (see also EINECS and ELINCS).
- EEC: European Economic Community.
- EEA: European Economic Area (EU + Iceland, Liechtenstein and Norway).
- EINECS: European Inventory of Existing Commercial Chemical Substances.
- ELINCS: European List of Notified Chemical Substances.
- EN: European Norm.
- EU: European Union.
- EWC: European Waste Catalogue (replaced by LoW – see below).
- GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
- IATA: International Air Transport Association.
- ICAO-TI: Technical Instructions for the Safe Transport of Dangerous Goods by Air.
- IMDG: International Maritime Dangerous Goods.
- IMO: International Maritime Organization.
- IMSBC: International Maritime Solid Bulk Cargoes.
- IUCLID: International Uniform Chemical Information Database.
- IUPAC: International Union of Pure and Applied Chemistry.
- Kow: n-Octanol - Water Partition Coefficient.
- LC50: Lethal concentration resulting in 50 % mortality.
- LD50: Lethal dose resulting in 50 % mortality (median lethal dose).
- LoW: List of Waste.
- LOEC: Lowest Observed Effect Concentration.
- LOEL: Lowest Observed Effect Level.
- NOEC: No Observed Effect Concentration.
- NOEL: No Observed Effect Level.
- NOAEC: No Observed Adverse Effect Concentration.
- NOAEL: No Observed Adverse Effect Level.
- OECD: Organization for Economic Cooperation and Development.
- OSHA: Occupational Safety and Health Administration.
- PBT: Persistent, Bioaccumulative and Toxic.
- PNEC: Predicted No Effect Concentration.
- OSAR: Quantitative Structure Activity Relationship.
- REACH: Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.
- RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.
- SCBA: Self Contained Breathing Apparatus.
- SDS: Safety Data Sheet.
- STOT: Specific Target Organ Toxicity.
- SVHC: Substances of Very High Concern.



UN: United Nations.

UVCB: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials.

VOC: Volatile Organic Compound.

vPvB: very Persistent and very Bioaccumulative.

This safety data sheet had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations.

The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information.

The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product.

It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product.

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Safety data sheet was prepared by:  
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