



## MATERIAL SAFETY DATA SHEET

SDS-Clostridium difficile GDH+ToxinA+B Ed00

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

**Product name:** Vitassay Clostridium difficile GDH+Toxin A+B

**Composition:** Test + Sample diluent

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

**Relevant identified uses:**

- **Test:** Medical device for professional *in vitro* diagnostic use only. Detection of Clostridium difficile Glutamate Dehydrogenase (GDH), Toxin A and B in stool samples.

- **Sample diluent:** Use for *Clostridium difficile* GDH + Toxin A and Toxin B antigens extraction from stool samples. This buffer is only provided with the product which has to be used (Vitassay Clostridium difficile GDH+Toxin A+B).

**Uses advised against:** No information available.

#### 1.3. Company/undertaking identification

**Manufacturer:** Vitassay Healthcare S.L.U.

**Address:** Parque Tecnológico WALQA, Ctra. N.330, Km.566, 22197-Cuarte (Huesca, SPAIN)

**Telephone number:** +34 974001193

**Fax:** +34 974001193

**E-mail:** info@vitassay.com

**For more information visit:** www.vitassay.com

#### 1.4. Emergency telephone number:

**European Union emergency number:** 112

**Number of the company:** +34 974001193

### 2. HAZARD IDENTIFICATION

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

Non-hazardous preparation (Regulation 1272/2008/EC).

##### 2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]:

Non-hazardous.

##### 2.1.2. Classification according to Directive 1999/45/EC:

Non-hazardous.

##### 2.1.3 Additional information:

See SECTION 16.

#### 2.2. Label elements

**Signal Word:** None

#### 2.3. Other hazards:

No hazards know.



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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.1. Substances:

No information available.

#### 3.2. Mixtures

**Mixture description:** Sample diluent contains buffer, salt, detergent and <0.1% of sodium azide as preservative.

##### 3.2.1 Hazardous components:

Substance	CAS No.	CE No.	W/W %	Regulation (EC) no 1272/2008 [CLP]	Classification
Sodium azide (Preservative)	26628-22-8	247-852-1	<0.1	Acute Tox. 2: H300 Aquatic Acute 1: H400 Aquatic Chronic 1: H410	Due to concentration <0.1%, this preparation is not classified as dangerous on the basis of health and/or environment effects

Lowest generic cut-off value:  $\geq 0.1$

Lowest specific concentration limits/ M-factor: N/A (according to ATE Annex I section 3.1.3.6.1. and Table classification  $\geq 1.0$  %).

**Note:** Sample diluent is not dangerous preparation (Regulation (EC) No 1272/2008 [CLP]).

The device consists in three strips composed of several layers: an absorbent material pre-dried with a coloured latex-antibodies conjugate against the product antigens, a nitro-cellulose membrane with coated antibodies against the product antigens and cellulose absorbent. Contains sodium azide <0.1% as preservative.

**Additional information:** For full text of H-phrases: see SECTION 16.

### 4. FIRST-AID MEASURES

#### 4.1. Description of first aid measures

**Following eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.

**Following skin contact:** Wash off immediately with soap and plenty of water. Consult a physician.

**Following ingestion:** Clean mouth with water and drink afterwards plenty of water. Consult a physician.

**Following inhalation:** Ensure sufficient ventilation of workplace. Consult a physician.

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

No information available.

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

Treat symptomatically.

### 5. FIREFIGHTING MEASURES

#### 5.1. Extinguishing media

**Suitable Extinguishing Media:** Water or CO<sub>2</sub>. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Extinguishing media which must not be used for safety reasons:** No information available.



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### **5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors.

### **5.3. Advice for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## **6. ACCIDENTAL RELEASE MEASURES**

### **6.1. Personal precautions, protective equipment and emergency procedures**

Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation.

### **6.2. Environmental precautions**

Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

### **6.3. Methods and material for containment and cleaning up**

Soak up with inert absorbent material. Clean contaminated surface thoroughly.

### **6.4. Reference to other sections**

If appropriate Sections 8 and 13 shall be referred to.

## **7. HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

Good Laboratory Practices (disposal gloves). Not to eat, drink and smoke in work areas. Avoid contact and contamination with skin, eyes and clothes. Use disposal gloves. Specimens should be handled as potentially infectious materials.

### **7.2. Conditions for safe storage, including any incompatibilities**

Store in a dry place at +2°C to +30°C. Avoid storage near to heat sources.

### **7.3. Specific end use(s)**

Only use provided diluent for sample dilution.



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

Any specific protection and prevention measures should not be taken during use of the product.  
Exposure limits:

Substance	LTEL (8 hr)	STEL
Sodium azide (NaN <sub>3</sub> )	mg/m <sup>3</sup>	mg/m <sup>3</sup>
CAS No. 26628-22-8	0.1	0.3

#### 8.2. Exposure controls

All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

##### 8.2.1. Appropriate engineering controls

No relevant for this material.

##### 8.2.2. Personal protective equipment

Handle with disposable gloves (EN 374). Wear appropriate protective safety eyewear and clothing, such as a lab coat.

##### 8.2.3. Environmental Exposure Controls

No special measures are required.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

**Appearance/Physical State:** Test: White solid with yellow lines. Solid reaction strip that is packaged depending on the format used. Sample diluent: Transparent slightly yellowish.

**The following table only applies to sample diluent:**

<b>Odor:</b> Odourless <b>pH:</b> 7.5-8.5 <b>Boiling Point:</b> Similar to water (100°C) <b>Flash Point:</b> Not applicable <b>Vapor Pressure:</b> Similar to water (23hPa) <b>Melting Point:</b> Similar to water (0°C) <b>Autoignition Temperature:</b> Not determined <b>Partition Coefficient (n-octanol/water):</b> Not determined	<b>Explosion Limits:</b> Not applicable <b>Vapor Density:</b> Not determined <b>Relative density:</b> Similar to water (1g/cm <sup>3</sup> ) <b>Solubility:</b> Soluble <b>Flammability:</b> Not applicable <b>Viscosity:</b> Not determined <b>Explosive Properties:</b> Not explosive <b>Oxidizing Properties:</b> Not determined
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### 10. STABILITY AND REACTIVITY

#### 10.1. Reactivity

No hazardous reactivity known.

#### 10.2. Chemical stability

Under storage at normal ambient temperatures the product is stable. No known hazardous reactions.

#### 10.3. Possibility of hazardous reactions

Thermal decomposition can lead to release of irritating gases and vapors.

#### 10.4. Conditions to avoid

Direct contact with a flame. Temperatures outside the range of 2-30 ° C. Avoid storing in places with high humidity.

#### 10.5. Incompatible materials

The stool sample should be treated only with buffer that is provided with the product before testing.

#### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

### 11. TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

**Acute toxicity:** Product does not present an acute toxicity hazard based on known or supplied information. Oral LD<sub>50</sub> Rat: 27mg/kg; Dermal LD<sub>50</sub> Rabbit: 20mg/kg.

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

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

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

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

**Carcinogenicity:** A4-Not classifiable as a Human Carcinogen.

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

**Summary of evaluation of the CMR properties:** Based upon the available data, the classification criteria are not met.

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

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

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

### 12. ECOLOGICAL INFORMATION

#### 12.1. Toxicity

Based upon the available data, the classification criteria are not met. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

#### 12.2. Persistence and degradability

Based upon the available data, the classification criteria are not met.



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### 12.3. *Bioaccumulative potential*

Based upon the available data, the classification criteria are not met.

### 12.4. *Mobility in soil*

Based upon the available data, the classification criteria are not met.

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

No data available for assessment.

### 12.6. *Other adverse effects*

Based upon the available data, the classification criteria are not met.

## 13. DISPOSAL CONSIDERATIONS

### 13.1. *Waste treatment methods*

**Waste from Residues:** After testing, the product must be disposed of compliance with the respective local, state or national regulations. One option would be possible inactivation of infectious agents in the product after use. Performed in autoclave at a pressure and a certain temperature.

**Non-contaminated packaging:** The containers can be recycled.

## 14. TRANSPORT INFORMATION

**Maritime transport (IMDG/IMO):** Not dangerous preparations not required transport regulations.

**Land transport (ADR):** Not dangerous preparations not required transport regulations.

**Air Transport (IATA):** Not dangerous preparations not required transport regulations.

## 15. REGULATORY INFORMATION

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

This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for *in vitro* diagnosis, so they must meet the criteria described in Directive 98/79/CE, do not carry the CE marking for marketing outside the EU.

The product is a mixture which is not subject to Regulation (EC) No 1005/2009, (EC) No 850/2004.

**National Regulations:** Please ask your national/regional authorities.

### 15.2. *Chemical Safety Assessment*

A Chemical Safety Assessment/Report has not been conducted.

## 16. OTHER INFORMATION

### 16.1. *Recommendations:*

Consult instructions for use prior to product use. Professional use only for *in vitro* diagnosis.



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### 16.2. References (previous version)

**RD 255/2003, of February 28**, approving the Regulation on classification, packaging and labeling of dangerous preparations, which incorporates into Spanish law **Directive 1999/45/CE**, **Directive 2001/60/CE** and partly **Directive 2001/58/CE**. **Directive 91/155/CE**.

### 16.3. Changes

Update in accordance with **Regulation (EC) No 1272/2008** and **EU No 2015/830** (changes to all sections).

### 16.4. Abbreviations and acronyms

<b>STOT:</b>	Specific Target Organ Toxicity	<b>ATE:</b>	Acute toxicity estimate
<b>STEL:</b>	Short Term Exposure Limit	<b>LD:</b>	Lethal Dose
<b>LTEL:</b>	Long Term Exposure limit	<b>Acute Tox. 2:</b>	Acute toxicity: Category 2
		<b>Aquatic Acute 1:</b>	Hazardous to the aquatic environment
<b>GHS:</b>	Global Hazard Symbol		Acute: Category 1
<b>PBT:</b>	Persistent, Bioaccumulative and Toxic	<b>Aquatic Chronic 1:</b>	Chronic Aquatic toxicity: Category 1
<b>vPvB:</b>	very Persistent and very Bioaccumulative		

### 16.5. Key literature references and sources for data

See instruction for use, Safety Data sheet and ECHA.

### 16.6. Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Annex I section 3 and 4; Annex VI Table 3.1 of **Regulation (EC) No 1272/2008** was used for the purpose of classification.

### 16.7. Relevant H-statements (number and full text)

<b>H300:</b>	Fatal if swallowed
<b>H400:</b>	Very toxic to aquatic life.
<b>H410:</b>	Very toxic to aquatic life with long lasting effects

### 16.8. Training advice

No special training is required.



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### 16.9. Contact

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**For more information visit:** [www.vitassay.com](http://www.vitassay.com)

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The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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