MATERIAL SAFETY DATA SHEET

SDS-Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus Ed00

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

1.1. Product identifier

Product name: Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus
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. Use for detection of rotavirus, adenovirus, astrovirus, norovirus and enterovirus in stool samples.

- Sample diluent: Use for rotavirus, adenovirus, astrovirus, norovirus and enterovirus antigens extraction from stool samples. This buffer is only provided with the product which has to be used (Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus).

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.

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: ≥ 0.1
Lowest specific concentration limits/ M-factor: N/A (according to ATE Annex I section 3.1.3.6.1. and Table classification ≥ 1.0 %).
Note: Sample diluent is not dangerous preparation (Regulation (EC) No 1272/2008 [CLP]).

The device consists in four 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_2. 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.

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 +2ºC to +30ºC. Avoid storage near to heat sources.

7.3. Specific end use(s)

Only use provided diluent for sample dilution.

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_3)	**mg/m³**	**mg/m³**
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:

Odor: Odourless **pH:** 7.5-8.5 **Boiling Point:** Similar to water (100ºC) **Flash Point:** Not applicable **Vapor Pressure:** Similar to water (23hPa) **Melting Point:** Similar to water (0ºC) **Autoignition Temperature:** Not determined **Partition Coefficient (n-octanol/water):** Not determined	**Explosion Limits:** Not applicable **Vapor Density:** Not determined **Relative density:** Similar to water (1g/cm^3) **Solubility:** Soluble **Flammability:** Not applicable **Viscosity:** Not determined **Explosive Properties:** Not explosive **Oxidizing Properties:** Not determined

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_{50} Rat: 27mg/kg; Dermal LD_{50} 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.

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.

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

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

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

16.8. Training advice

No special training is required.

16.9. Contact

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