SAMPLE EXTRACTION BUFFER – ROTAVIRUS RAPYDTEST®



This Safety Datasheet complies with the requirements of Regulation (EC) No 1907/2006

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

1.1 **Product Identifier:** 1641 Sample Extraction Buffer Rotavirus Ag Rapydtest[®]

1.2 Relevant identified uses of the substance or mixture and uses advised against: Lateral flow immunochromatographic assay for the qualitative detection of antigen in human faecal specimens. These tests are for in vitro use only.

1.3 Details of the supplier of the Safety Data Sheet:

Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, Berkshire, RG41 2QL, England +44 (0) 118 979 5566 technical@apacor.com

1.4 Emergency telephone number:

+44 (0)118 979 5566 (Monday-Friday 0900-1700 excluding UK Public Holidays)

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]: Not classified as hazardous in concentration of <0.1% (Sodium Azide).

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP] The product does not contain a hazardous ingredient in an amount that requires identification and labelling according to the concentration limit/cut-off values of EC directives. This product contains no hazardous constituents, or the concentration of all chemical constituents is below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200 and the European Directive 91/155/EEC, 93/112/EC and (EC) 1272/2008 (CLP).

Pictogram: None Signal Word: -Hazard statement(s): -

Precautionary statements:-

2.3 Other hazards

Bio-hazards: All the biological substances are derived from in vitro culture system or animal materials which are free of known-pathogens for human. Thus, no bio-hazardous can be claimed in the product.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS 3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Substance Name: Sodium Azide CAS #: 26628-22-8 Index No: -

EC Number: 247-852-1

Classification: Acute Tox. 2 (H300), Aquatic Acute 1 (H400), Aquatic Chronic 1 H410, EUH032

Amount: 0.09%

See Section 16 for the full text of H-Statements mentioned in this Section.

Note: The strip is composed of nitrocellulose membrane, vinyl matte adhesive, fibre absorbent pad, fibre sample pad, fibre conjugate pad. The nitrocellulose membrane and the fibre conjugate pad contain dried biological substances preserved by sodium azide. The identity of each biological substance is confidential.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled: Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

In case of skin contact: The Sample Extraction Buffer is not likely to be hazardous by skin contact. However, in case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fibre conjugate pad are very unlikely to be hazardous by skin contact, but cleaning the skin after use is advisable.

If swallowed: Ingestion of small amounts of the Sample Extraction Buffer should not be toxic, however, a physician should be consulted immediately. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fibre conjugate pad are very unlikely to be ingested or be hazardous by ingestion. However, a physician should be consulted should ingestion occur.

In case of eye contact: The test device is very unlikely to come into contact with the eye, however, a physician should be consulted should contact occur. In case of contact with the Sample Extraction Buffer, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Aggravating Condition: Repeated or prolonged exposure is not known to aggravate medical conditions.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (Section 2.2) and/or Section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

For small fires, use dry chemical, carbon dioxide, or alcoholresistant foam. No direct contact with water.

5.2 Special hazards arising from the substance or mixture This material will not significantly contribute to the intensity

of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-

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Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 Advice for firefighters

When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., carbon monoxide, carbon dioxide, sulfuric dioxide). Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions. Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Lab coat and gloves.

6.2 Environmental precautions No data available.

6.3 Methods and material for containment and cleaning up

Use absorbent paper towel or cloth to absorb the spill solution and dispose or clean the contaminated surface in accordance with local procedures or appropriate standards

6.4 Reference to other sections

For disposal, see Section 13.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not eat, drink, smoke or apply cosmetics in laboratory area. Use the product according to the product insert.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep product at 2-30°C. Do not freeze or expose to temperature higher than 30°C. Keep away from children.

7.3 Specific end use(s)

No other specific uses are specified apart from those listed in Section 1.2.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters					
CAS #	Chemical	OSHA (PEL)	ACGIH (TLV)*	MAK	
	Name				
26628-22-8	Sodium Azide	0.3mg/m ³	0.29mg/m ³	0.2mg/m ³	

Biological Exposure Index (ACGIH)

Other exposure limits for potential decomposition products: None.

8.2 Exposure controls

Engineering Control: Eye bath. Use adequate ventilation to keep airborne concentrations low.

Hygiene Measures: Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of the day.

Personal Protective Equipment:

Respiratory Protection: None needed under normal conditions of use.

Skin and Body: Lab coat as indicated by general lab practice guidelines.

Eyes: Safety glasses or face shield are recommended to prevent eye contact.

Hand: Compatible chemical resistant gloves.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- a) Appearance Form: liquid
- b) Odour odourless
- c) Odour threshold no data available
- d) pH no data available
- e) Melting point / freezing point 275
- f) Initial boiling point and boiling range no data available
- g) Flash point non-combustible
- h) Evaporation rate no data available
- i) Flammability (solid, gas) no data available
- j) Upper/lower flammability or explosive limits not applicable
- k) Vapour pressure no data available
- I) Vapour density 2.2
- m) Relative density no data available
- n) Solubility (ies) 42% at 17°C (water)
- o) Partition coefficient: n-octanol/water no data available
- p) Auto-ignition temperature not applicable
- q) Decomposition temperature no data available
- r) Viscosity no data available
- s) Explosive properties no data available
- t) Oxidising properties no data available

9.2 Other information No data available

SECTION 10 STABILITY AND REACTIVITY 10.1 Reactivity

No data available.

10.2 Chemical stability Stable under normal storage conditions.

10.3 Possibility of hazardous reactions Acids, metals, caustics, acid chlorides, peroxides and hydroperoxides, and oxidizing agents.

10.4 Conditions to avoid

Contact with acids, metals, caustics, acid chlorides, peroxides and hydroperoxides, and oxidizing agents. **10.5 Incompatible materials** >250°C

10.6 Hazardous decomposition products

Nitrogen oxides, nitrogen, hydrazoic acid

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SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information of toxicological effects

No adverse effects on the health are expected from the components of the product. There is no aquatic toxicity data for this product at this time. Individual aquatic toxicity studies have been completed for the below listed chemicals.

Sodium Azide RTECS Number: VYB050000

Acute toxicity: no data available

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitisation: no data available

Germ cell mutagenicity: no data available

Carcinogenicity: IARC: no component of this product present at levels greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity: no data available

Specific target organ toxicity - single exposure: no data available

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

Additional Information

Sodium Azide	Toxicity Data & References:	Toxicology Review Reference FNSCA6 2:67, 1973	
	Orl; hmn: TDLo: 710 μg/kg	JCPAAK 28:350, 1975.	
	Orl; man: LDLo: 143 mg/kg	JTCTDW 24:339, 1986.	
	Orl; wmn: LDLo: 14 mg/kg	Arrythmias JFSCAS 35: 193, 1990.	
	ipr; rat: LdLo: 30mg/kg	PHRPA6 58:607, 1943.	
	Genetic Data & References:		
	Fbr; hmn: Dose: 50mg/L DNA inhibition STBIBN 78: 165, 1980. Lvr; rat; Dose: 1 mmol/L Mutations in mammalian somatic cells MUREAV 77:293, 1980.		

Tumorigenic Data References:

Orl; rat; Dose: 2730 mg/kg/ 78W-C Skin, appendage and endocrine system tumours. JJIND8 67:75, 1981. Orl; rat; Dose: 5460 mg/kg/ 78W-C Skin, appendage and endocrine

Orl; rat; Dose: 5460 mg/kg/ 78W-C Skin, appendage and endocrine system tumours. JIIND8 67:75, 1981.

Refer to the Registry of Toxic Effects of Chemical Substances (RTECS) for definitions of abbreviations used in the above text and for additional information. This report contains only selected information from the RTECS.

SECTION 12 ECOLOGICAL INFORMATION 12.1 Toxicity

Dangerous to the environment. Very toxic to aquatic organisms; may cause long term adverse effects in the aquatic environment. Freshwater Fish Species Data: 96 Hr LC50 Oncorhynchus mykiss: 0.8 mg/L;

96 Hr LC50 Lepomis macrochirus: 0.7 mg/L;

96 Hr LC50 Pimephales promelas: 5.46 mg/L [flow-through]

12.2 Persistence and degradability

When released into the soil, this material is not expected to biodegrade. When released into the soil, this material is expected to leach into groundwater. When released into the air, this material may be moderately degraded by photolysis.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

No data available.

12.7 Additional information

There is limited potential for the components within this product to accumulate in plant or animal systems.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste must be disposed of in accordance with federal, state and local environmental control regulations. *This product is not considered a RCRA hazardous waste*.

Accumulation of sodium azide in the sink may form highly explosive metal azides. Do not dispose the solid product into the sink.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number none

14.2 UN proper shipping name none

14.3 Transport hazard class(es) This substance is considered to be non-hazardous for transport.

14.4 Packing group none

14.5 Environmental hazards Do not discharge effluent containing this kit into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact the appropriate environmental agency.

14.6 Special precautions for user no data available

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not intended to be transported in bulk.

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture No data available.

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this product.

SECTION 16 OTHER INFORMATION

Full text of H-Statements referred to in Sections 2 and 3 H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long-lasting effects. EUH032 Contact with acids liberates very toxic gas.

The information supplied in this SDS is correct to the best of our knowledge. We do not accept any liability for loss, injury or damage, which may result from its use.