SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	ImmunoCard STAT!® CryptoGiardia Rapid Assay Sample Treatment Buffer
Registration number	-
Synonyms	Enterics Sample Treatment Buffer
Kit number	750830
Issue date	22-May-2012
Version number	02
Revision date	14-December-2012
Supersedes date	14-December-2012

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

Identified uses	Component of ImmunoCard STAT!® Crypto/Giardia Rapid Assay. For use in the ImmunoCard STAT! Crypto/Giardia Rapid Assay for the qualitative detection of Cryptosporidium parvum and Giardia lamblia specific antigens in aqueous extracts of fecal specimens. For In Vitro Diagnostic use only.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042
Distributor	Sekisui Diagnostics (UK) Limited 50 Gibson Drive, Kings Hill, West Malling Kent ME19 4AF UK www.sekisuidiagnostics.com Phone: 44 (0) 1732 220022
Contact person	info@sekisuidiagnostics.com
1.4. Emergency telephone number	Americas 1-760-476-3962 Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960
Access code	333512

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

This preparation is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary

Physical hazards	Not classified for physical hazards.
Health hazards	Not classified for health hazards.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms	Ingestion may cause irritation and malaise.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

Precautionary statements

Prevention	None.
Response	None.
Storage	None.
Disposal	None.

Supplemental label information Not applicable.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sodium azide	0.1	26628-22-8 247-852-1	-	011-004-00-7	#

Classification: **DSD:** T+;R28, R32, N;R50/53

CLP: Acute Tox. 2;H300, Aquatic Acute 1;H400, Aquatic Chronic 1;H410

#: This substance has been assigned Community workplace exposure limit(s).
DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.

Composition comments The full text for all R- and H-phrases is displayed in section 16. All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical attention if irritation develops and persists.

4.2. Most important symptoms and effects, both acute and delayed Ingestion may cause irritation and malaise.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture When heated to decomposition, may produce hydrazoic acid fumes.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
For emergency responders	Use personal protection as recommended in section 8 of the SDS.
6.2. Environmental precautions	Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.
6.3. Methods and material for containment and cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	For use in the ImmunoCard STAT! Crypto/Giardia Rapid Assay for the qualitative detection of Cryptosporidium parvum and Giardia lamblia specific antigens in aqueous extracts of fecal specimens.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m3
	TWA	0.1 mg/m3

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m3
	TWA	0.1 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours.

Individual protection measures, such as personal protective equipment

General information	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear approved safety glasses or goggles.
Skin protection	
- Hand protection	Wear appropriate chemical resistant gloves.
- Other	Remove contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Clear, colourless liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Clear, colorless.
Odour	Not available.
Odour threshold	Not available.
pH	9 Approximate.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	Soluble in water.
Partition coefficient (n-octanol/water)	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Contact with acids liberates toxic gas.
10.4. Conditions to avoid	Heat, sparks, flames, elevated temperatures.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No data available.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	May cause discomfort if swallowed.
Inhalation	Vapours may irritate throat and respiratory system and cause coughing.
Skin contact	May cause skin irritation.
Eye contact	May cause eye irritation.
Symptoms	Ingestion may cause irritation and malaise.

11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.

Components	Species	Test results
Sodium azide (CAS 26628-22-8)		
Acute		
Dermal		
LD50	Rabbit	20 mg/kg
Oral		
LD50	Rat	27 mg/kg

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/irritation May cause eye irritation.

Respiratory sensitisation Not classified.

Skin sensitisation Not classified.

Germ cell mutagenicity Not classified.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Not classified.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not classified.

Mixture versus substance information Not available.

Other information No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test results
Sodium azide (CAS 26628-22-8)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia pulex)	2.8 - 6.2 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	0.68 mg/l, 96 hours

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow) Not applicable.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Not available.

Mobility in general The product is soluble in water.

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions. This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.

SECTION 14: Transport information

ADR

The product is not covered by international regulation on the transport of dangerous goods.

RID

The product is not covered by international regulation on the transport of dangerous goods.

ADN

The product is not covered by international regulation on the transport of dangerous goods.

IATA

The product is not covered by international regulation on the transport of dangerous goods.

IMDG

The product is not covered by international regulation on the transport of dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This substance/mixture is 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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not regulated.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not regulated.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not regulated.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Sodium azide (CAS 26628-22-8)

Directive 94/33/EC on the protection of young people at work

Sodium azide (CAS 26628-22-8)

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

National regulations	The product has not been classified as dangerous according to the legislation in force.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	DNEL: Derived No-Effect Level. PNEC: Predicted No-Effect Concentration. LD50: Lethal Dose, 50%.
References	IARC Monographs. Overall Evaluation of Carcinogenicity HSDB (2005)
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R28 Very toxic if swallowed. R32 Contact with acids liberates very toxic gas. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H300 - Fatal if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Training information	Follow training instructions when handling this material.
Disclaimer	The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.