

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

1.1. Product identifier

Trade name or designation of the mixture Syphilis TPLA Calibrators & Controls

Registration number -

Synonyms None.

Part number 486661, 486654

Issue date 06-June-2012

Version number 01

Revision date -

Supersedes date -

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

Identified uses 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

Manufacturer Sekisui Medical Co Ltd.
13-5, Nihombashi 3-chome, Chuo-ku,
Tokyo, 103-0027 Japan

Distributor Sekisui Diagnostics (UK) Limited
50 Gibson Drive, Kings Hill, West Malling
Kent ME19 4AF UK
www.sekisuidiagnostics.com

Telephone number 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 substance 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. This product contains bovine serum albumin. This product contains Syphilis positive Plasma and should therefore be handled as a potentially biohazardous material in accordance with universal/standard precautions.

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 chloride	10 - 15	7647-14-5 231-598-3	-	-	
Classification:	DSD: - CLP: -				
Sucrose	10 - 15	57-50-1 200-334-9	-	-	
Classification:	DSD: - CLP: -				
Ethylene diamine tetraacetic acid, Tripotassium salt	3 - 7	17572-97-3 241-543-5	-	-	
Classification:	DSD: Xi;R36-37-38 CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335, STOT SE 3;H336				
Disodium hydrogen orthophosphate	1 - 3	7558-79-4 231-448-7	-	-	
Classification:	DSD: - CLP: -				
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 All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R-phrases is displayed in Section 16.

SECTION 4: First aid measures

General information Not available.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. 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	If material is ingested, immediately contact a physician or poison control centre.

4.2. Most important symptoms and effects, both acute and delayed Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.

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	None known.
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. This product contains Syphilis positive Plasma and should therefore be handled as a potentially biohazardous material in accordance with universal/standard precautions. Handle and open container with care.
7.2. Conditions for safe storage, including any incompatibilities	Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	For In Vitro Diagnostic use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Austria. MAK List Components

	Type	Value
Sodium azide (CAS 26628-22-8)	MAK	0,1 mg/m3
	STEL	0,3 mg/m3

Belgium. Exposure Limit Values. Components

	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
Sucrose (CAS 57-50-1)	TWA	0,1 mg/m3
	TWA	10 mg/m3

Bulgaria. OELs. Regulation No 13 on protection of workers against risks of exposure to chemical agents at work Components

	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
	TWA	0,1 mg/m3

Czech Republic. OELs. Government Decree 361 Components

	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0,3 mg/m3
	TWA	0,1 mg/m3

Denmark. Exposure Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	TLV	0,1 mg/m3

Estonia. OELs. Occupational Exposure Limits of Hazardous Substances. (Annex of Regulation No. 293 of 18 September 2001)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
Sucrose (CAS 57-50-1)	TWA	0,1 mg/m3
	TWA	10 mg/m3

Finland. Workplace Exposure Limits

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
	TWA	0,1 mg/m3

France. Threshold Limit Values (VLEP) for Occupational Exposure to Chemicals in France, INRS ED 984

Components	Type	Value
Sodium azide (CAS 26628-22-8)	VLE	0,3 mg/m3
Sucrose (CAS 57-50-1)	VME	0,1 mg/m3
	VME	10 mg/m3

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	TWA	0,2 mg/m3	Inhalable fraction.

Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace

Components	Type	Value
Sodium azide (CAS 26628-22-8)	AGW	0,2 mg/m3

Greece. OELs (Decree No. 90/1999, as amended)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
	TWA	0,1 ppm
		0,3 mg/m3
		0,1 ppm

Hungary. OELs. Joint Decree on Chemical Safety of Workplaces

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
	TWA	0,1 mg/m3

Iceland. OELs. Regulation 154/1999 on occupational exposure limits

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
	TWA	0,1 mg/m3

Ireland. Occupational Exposure Limits

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
Sucrose (CAS 57-50-1)	TWA	0,1 mg/m3
	STEL	20 mg/m3
	TWA	10 mg/m3

Italy. OELs

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3
Sucrose (CAS 57-50-1)	TWA	0,1 mg/m3
	TWA	10 mg/m3

Latvia. OELs. Occupational exposure limit values of chemical substances in work environment

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m3

Latvia. OELs. Occupational exposure limit values of chemical substances in work environment

Components	Type	Value
Sodium chloride (CAS 7647-14-5)	TWA	0,1 mg/m ³
	TWA	5 mg/m ³

Lithuania. OELs. Limit Values for Chemical Substances, General Requirements (Hygiene Norm HN 23:2007)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
Sodium chloride (CAS 7647-14-5)	TWA	0,1 mg/m ³
	TWA	5 mg/m ³
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

Malta. OELs. Occupational Exposure Limit Values (L.N. 227. of Occupational Health and Safety Authority Act (CAP. 424), Schedules I and V)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³

Netherlands. OELs (binding)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³

Norway. Administrative Norms for Contaminants in the Workplace

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0,3 mg/m ³

Poland. MACs. Minister of Labour and Social Policy Regarding Maximum Allowable Concentrations and Intensities in Working Environment

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³

Portugal. OELs. Decree-Law n. 290/2001 (Journal of the Republic - 1 Series A, n.266)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³

Portugal. VLEs. Norm on occupational exposure to chemical agents (NP 1796)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	Ceiling	0,29 mg/m ³
Sucrose (CAS 57-50-1)	TWA	0,11 ppm
		10 mg/m ³

Romania. OELs. Protection of workers from exposure to chemical agents at the workplace

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³

Slovakia. OELs. Decree of the government of the Slovak Republic concerning protection of health in work with chemical agents

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0,3 mg/m ³	
Sucrose (CAS 57-50-1)	TWA	0,1 mg/m ³	
	TWA	6 mg/m ³	Aerosol

Slovenia. OELs. Regulations concerning protection of workers against risks due to exposure to chemicals while working (Official Gazette of the Republic of Slovenia)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	TWA	0,1 mg/m ³

Spain. Occupational Exposure Limits

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³
Sucrose (CAS 57-50-1)	TWA	10 mg/m ³

Sweden. Occupational Exposure Limit Values

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³

Switzerland. SUVA Grenzwerte am Arbeitsplatz

Components	Type	Value	Form
Sodium azide (CAS 26628-22-8)	STEL	0,4 mg/m ³	Inhalable dust.
	TWA	0,2 mg/m ³	Inhalable dust.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium azide (CAS 26628-22-8)	STEL	0,3 mg/m ³
	TWA	0,1 mg/m ³
Sucrose (CAS 57-50-1)	STEL	20 mg/m ³
	TWA	10 mg/m ³

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/m ³
	TWA	0,1 mg/m ³

Biological limit values**Hungary. Chemical Safety at Workplace Ordinance Joint Decree No. 25/2000 (Annex 2): Permissible limit values of biological exposure (effect) indices**

Components	Value	Determinant	Specimen	Sampling time
Disodium hydrogen orthophosphate (CAS 7558-79-4)	25 %	red blood cell or total blood acetylcholinesterase activity (EC. 3.1.1.7.)	Reduction from individual baseline activity in red blood cells	Sampling time: Not critical.
Sodium azide (CAS 26628-22-8)	25 %	red blood cell or total blood acetylcholinesterase activity (EC. 3.1.1.7.)	Reduction from individual baseline activity in red blood cells	Sampling time: Not critical.

Recommended monitoring procedures Follow standard monitoring procedures.

8.2. Exposure controls

Appropriate engineering controls Use general ventilation.

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 Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection Under normal conditions, respirator is not normally required.

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	Liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not applicable.
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)	Not available.
Partition coefficient (n-octanol/water)	Not available.
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	Protect against direct sunlight.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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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	Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed through the skin and result in systemic effects.
Eye contact	Splashes in the eyes may cause redness and irritation.
Symptoms	May cause eye irritation on direct contact.

11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
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Components	Species	Test results
Disodium hydrogen orthophosphate (CAS 7558-79-4)		
Acute		
<i>Oral</i>		
LD50	Rat	17 g/kg
Sodium azide (CAS 26628-22-8)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	20 mg/kg
<i>Oral</i>		
LD50	Rat	27 mg/kg
Sucrose (CAS 57-50-1)		
Acute		
<i>Oral</i>		
LD50	Rat	29700 mg/kg
Skin corrosion/irritation	Sodium azide may be absorbed through the skin and result in systemic effects.	
Serious eye damage/irritation	Splashes in the eyes may cause redness and irritation.	
Respiratory sensitization	Not classified.	
Skin sensitization	Not classified.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classified.	
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 Not expected to be harmful to aquatic organisms.

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	No data available.	
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.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	Waste codes should be assigned by the user based on the application for which the product was used.

Disposal methods/information Dispose in accordance with all applicable regulations. 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.

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	This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 1999/45/EC and their amendments respectively. 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 been classified 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. PBT: Persistent, bioaccumulative and toxic. vPvB: Very Persistent and very Bioaccumulative.
References	IARC Monographs. Overall Evaluation of Carcinogenicity HSDB
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. R36 Irritating to eyes. R37 Irritating to respiratory system. R38 Irritating to skin. R50/53 Very toxic to aquatic organisms, May cause long-term adverse effects in the aquatic environment. H300 - Fatal if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. H336 - May cause drowsiness or dizziness. 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.