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	Nanopia KL-6 Calibrator
Registration number	-
Synonyms	None.
Part Number	ES336928
Issue date	28-May-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 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 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. Bovine source materials. Treat as potentially infectious. Bovine based products should be handled in accordance with good laboratory practices using appropriate 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

The components are not hazardous or are below required disclosure limits.

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. 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	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
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	7,5
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	Hazardous polymerization will not occur.
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.

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.
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.
12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	No data available.
Partition coefficient n-octanol/water (log Kow)	Not 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

Not listed.

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

Not listed.

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	None.
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.