Safety Data Sheet

Material Name Nanopia™ D-dimer Control Set **MsdsId CA-126**

* * *Section 1 - IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING* * *

1.1 Product Identifier:

Material Name: Nanopia™ D-dimer Control Set Catalog No. 491610

Substance Registration Number(s)

This product and its components are not subject to REACH.

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Identified Uses

in vitro diagnostic use

Uses Advised Against

Use in accordance with supplier's recommendations.

1.3 Details of the supplier of the safety data sheet

Sekisui Medical Co., Ltd.
KDX-Nihonbashi Building, 3-13-5
Nihonbashi, Chuo-ku,
Tokyo 103-0027, Japan
Phone: +81-3-3272-0679

European Distributors:

Sekisui Diagnostics (UK) Ltd.
50 Gibson Drive, Kings Hill, West Malling
Kent ME19 4AF UK
www.sekisuidiagnostics.com
Phone: 44 (0) 1732 220022

SekisuiVirotech GmbH
Loewenplatz 5, 65428 Ruesselsheim
Germany
www.sekisuivirotech.com
Phone: 0049172 6167673

* * *Section 2 - HAZARDS IDENTIFICATION* * *

2.1 Classification of the Substance or Mixture

Classification according to Regulation (EC) No 1272/2008

No classification is assigned, based on classification criteria. Review the entire data sheet for any additional information which did not result in a GHS classification.

Classification according to Directives 67/548/EEC and/or 1999/45/EC

No classification is assigned, based on classification criteria. Review the entire data sheet for any additional information which did not result in a GHS classification.

2.2 Label Elements

Labeling according to Regulation (EC) 1272/2008/EC:

Symbol(s)

None needed according to classification criteria.

Signal Word

None needed according to classification criteria.

Hazard Statement(s)

None needed according to classification criteria.

Precautionary Statement(s)

Prevention

None needed according to classification criteria.

Response
None needed according to classification criteria.

Storage
None needed according to classification criteria.

Disposal
Dispose in accordance with all applicable regulations.

Labelling according to Directive 67/548/EEC and/or 1999/45/EC
None needed according to classification criteria.

2.3 Other Hazards
None known.

* * *Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS* * *

CAS EC No Registration No	Component Synonyms	67/548 EEC (DSD)	1272/2008 (CLP)	Percent
57-50-1 200-334-9 --	Sucrose			<20
7647-14-5 231-598-3 --	Sodium chloride	Xi; R:36		<1
77-86-1 201-064-4 --	Tris (hydroxymethyl) aminomethane	Xi; R:36-37-38		<0.5
Proprietary -- --	ProClin 300			<0.1

* * *Section 4 - FIRST AID MEASURES* * *

4.1 Description of First Aid Measures

Inhalation
If adverse effects occur, remove to uncontaminated area. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention.

Skin
Wash with plenty of soap and water. Seek medical attention if irritation develops.

Eyes
Flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. If irritation or pain persists after fifteen minutes of eye irrigation, seek medical attention.

Ingestion
If swallowed, get medical attention.

4.2 Most Important Symptoms and Effects, both Acute and Delayed

Acute
No information available for the product.

Delayed
No information available for the product.

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed

Note to Physicians
Treat symptomatically and supportively.

* * *Section 5 - FIRE FIGHTING MEASURES* * *

5.1 Extinguishing Media

Use extinguishing agents appropriate for surrounding fire.

Unsuitable Extinguishing Media

Do not use high-pressure water streams.

5.2 Special Hazards Arising from the Substance or Mixture

Negligible fire hazard.

5.3 Advice for Firefighters

Fire Fighting Measures

Move container from fire area if it can be done without risk. Cool containers with water spray until well after the fire is out.

Protective Equipment and Precautions for Firefighters

Wear self-contained breathing apparatus and protective clothing.

* * *Section 6 - ACCIDENTAL RELEASE MEASURES* * *

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Wear personal protective clothing and equipment, see Section 8.

6.2 Environmental Precautions

Avoid release to the environment.

6.3 Methods and Material for Containment and Cleaning up

Collect spilled material in appropriate container for disposal.

6.4 Reference to Other Sections

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations. See Section 13 for Disposal Considerations.

* * *Section 7 - HANDLING AND STORAGE* * *

7.1 Precautions for Safe Handling

Wash thoroughly after handling.

7.2 Conditions for Safe Storage, Including any Incompatibilities

Store and handle in accordance with all current regulations and standards.

7.3 Specific End Use(s)

None known.

* * *Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION* * *

8.1 Control Parameters

Component Exposure Limits

Sucrose (57-50-1)

Belgium:	10 mg/m3 TWA
France:	10 mg/m3 TWA
Ireland:	10 mg/m3 TWA
	20 mg/m3 STEL
Portugal:	10 mg/m3 TWA [VLE-MP]
Spain:	10 mg/m3 TWA [VLA-ED]
United Kingdom:	10 mg/m3 TWA
	20 mg/m3 STEL
	10 mg/m3 TWA

Biological Limit Value

There are no biological limit values for any of this product's components

Derived No Effect Levels (DNELs)

No DNELs available.

Predicted No Effect Concentrations (PNECs)

No PNECs available.

8.2 Exposure Controls

Engineering Controls

Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

Eye / Face Protection

Wear chemical safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

Skin Protection

Wear appropriate chemical resistant clothing.

Glove Recommendations

Wear appropriate chemical resistant gloves.

Respiratory Protection

Approved respirators should be worn when airborne concentrations are expected to exceed occupation exposure limits.

Follow the respiratory regulations found in European Standard EN 149.

Environmental Exposure Controls

Avoid release to the environment.

* * *Section 9 - PHYSICAL AND CHEMICAL PROPERTIES* * *

9.1 Information on Basic Physical and Chemical Properties

Physical State:	Solid	**Appearance:**	Solid
Color:	white to orange yellow	**Physical Form:**	Solid
Odor:	Not Available	**Odor Threshold:**	Not available
pH:	Not available	**Melting Point:**	Not available
Boiling Point:	Not available	**Flash Point:**	Not available
Decomposition:	Not available	**Evaporation Rate:**	Not available
LEL:	Not available	**UEL:**	Not available
Vapor Pressure:	Not available	**Vapor Density (air = 1):**	Not available
Density:	Not available	**Specific Gravity (water = 1):**	Not available
Water Solubility:	Not available	**Log KOW:**	Not available
Coeff. Water/Oil Dist:	Not available	**Auto Ignition:**	Not available
Viscosity:	Not available		

9.2 Other Information

* * *Section 10 - STABILITY AND REACTIVITY* * *

10.1 Reactivity

No reactivity hazard is expected.

10.2 Chemical Stability

Stable at standard temperatures and pressure.

10.3 Possibility of Hazardous Reactions

Will not polymerize.

10.4 Conditions to Avoid

None known.

10.5 Incompatible Materials

None known.

10.6 Hazardous Decomposition Products

No information available for the product.

* * *Section 11 - TOXICOLOGICAL INFORMATION* * *

11.1 Information on Toxicological Effects

Acute and Chronic Toxicity

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

Sucrose (57-50-1)

Oral LD50 Rat 29700 mg/kg

Sodium chloride (7647-14-5)

Inhalation LC50 Rat >42 g/m3 1 h; Oral LD50 Rat 3 g/kg; Dermal LD50 Rabbit >10 g/kg

Tris (hydroxymethyl) aminomethane (77-86-1)

Oral LD50 Rat 5900 mg/kg

Irritation / Corrosivity

No information available for the product.

Respiratory Sensitization

No information available for the product.

Skin Sensitization

No information available for the product.

Germ Cell Mutagenicity

No information available for the product.

Carcinogenicity

Component Carcinogenicity

None of this product's components are listed by IARC or DFG.

Reproductive Toxicity

No information available for the product.

Specific Target Organ Toxicity - Single Exposure

No target organs identified.

Specific Target Organ Toxicity - Repeated Exposure

No target organs identified.

Aspiration Hazard

No information available for the product.

* * *Section 12 - ECOLOGICAL INFORMATION* * *

12.1 Toxicity

Component Analysis - Aquatic Toxicity

Sodium chloride (7647-14-5)

Fish: 96 Hr LC50 Lepomis macrochirus: 5560-6080 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 6020-7070 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7050 mg/L [semi-static]; 96 Hr LC50 Pimephales promelas: 6420-6700 mg/L [static]; 96 Hr LC50 Oncorhynchus mykiss: 4747-7824 mg/L [flow-through]

Invertebrate: 48 Hr EC50 Daphnia magna: 1000 mg/L; 48 Hr EC50 Daphnia magna: 340.7 - 469.2 mg/L [Static]

12.2 Persistence and Degradability

No information available for the product.

12.3 Bioaccumulative Potential

No information available for the product.

12.4 Mobility in Soil

No information available for the product.

12.5 Results of PBT and vPvB Assessment

No information available.

EU - Interim Strategy for Management of PBT and vPvB Substances (PBT Assessments)

No components of this material are listed.

12.6 Other Adverse Effects

No information available.

* * *Section 13 - DISPOSAL CONSIDERATIONS* * *

13.1 Waste Treatment Methods

Dispose in accordance with all applicable regulations.

* * *Section 14 - TRANSPORT INFORMATION* * *

Transportation

Not regulated as a hazardous material for transportation.

International Bulk Chemical Code

This material does not contain any chemicals required by the IBC Code to be identified as dangerous chemicals in bulk.

* * *Section 15 - REGULATORY INFORMATION* * *

15.1 Safety, Health and Environmental Regulations / Legislation Specific for the Substance or Mixture

EU - REACH (1907/2006) - Annex XIV List of Substances Subject to Authorisation

No components of this material are listed.

EU - REACH (1907/2006) - Article 59(1) Candidate List of Substances Subject to Authorisation

No components of this material are listed.

EU - REACH (1907/2006) - Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

No components of this material are listed.

EU - REACH (1907/2006) - Potential Substances of Very High Concern

No components of this material are listed.

EU - Biocides (1451/2007) - Existing Active Substance

Sodium chloride (7647-14-5)

EU Biocidal Present

EU - REACH (1907/2006) - Article 15(2) - Substances Regarded as Being Registered - Biocidal Products

No components of this material are listed.

Germany Regulations

Germany Water Classification

Sodium chloride (7647-14-5)

ID Number 270, hazard class 1 - low hazard to waters

Tris (hydroxymethyl) aminomethane (77-86-1)

ID Number 4650, hazard class 2 - hazard to waters

Denmark Regulations

Environmental Protection Agency List of Undesirable Substances

No components of this material are listed.

Substance Analysis - Inventory

Component	CAS	EEC
Sucrose	57-50-1	EIN
Sodium chloride	7647-14-5	EIN
Tris (hydroxymethyl) aminomethane	77-86-1	EIN

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for the substance/mixture.

* * *Section 16 - OTHER INFORMATION* * *

16.1 Indication of changes

New SDS: February 29, 2012

16.2 Key / Legend

ADR - European Road Transport; CAS No. - Chemical Abstract Service Registry Number; CLP - Classification, Labelling and Packaging; EINECS - European Inventory of Existing Commercial Chemical Substances; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC Code - International Bulk Chemical Code; ICAO - International Civil Aviation Organization; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration, 50%; LD50 - Lethal Dose, 50%; LEL - Lower Explosive Limit; REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - European Rail Transport; STEL - Short-term Exposure Limit; TWA - Time Weighted Average; UEL - Upper Explosive Limit

16.3 Key literature references and sources for data

Available upon request

16.4 Methods used for classification of mixture according to Regulation (EC) No 1272/2008

Available upon request

16.5 Full text of R phrases in Section 3

R36 Irritating to eyes.

R37 Irritating to respiratory system.

R38 Irritating to skin.

16.6 Training Advice

Read the Safety Data Sheet before handling product.

16.7 Other Information

Disclaimer: Supplier gives no warranty whatsoever, including the warranties of merchantability or of fitness for a particular purpose. Any product purchased is sold on the assumption the purchaser shall determine the quality and suitability of the product. Supplier expressly disclaims any and all liability for incidental, consequential or any other damages arising out of the use or misuse of this product. No information provided shall be deemed to be a recommendation to use any product in conflict with any existing patent rights.

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