# SAFETY DATA SHEET



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

1.1. Product identifier

Trade name or designation

OSOM® Mono Test Diluent, ImmunoCard STAT Mono Diluent, Sure-Vue Signature Mono Diluent

of the mixture

Registration number -

Synonyms None.

**Kit number** 145, 755725, 23-200-275

Issue date 22-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 Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For use in the qualitative detection

of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in

the diagnosis of infectious mononucleosis. 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 info@sekisuidiagnostics.com Americas 1-760-476-3962

1.4. Emergency telephone

number

**Contact person** 

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

Classification Xn;R22

The full text for all R-phrases is displayed in section 16.

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

**Hazard summary** 

Physical hazards Not classified for physical hazards.

**Health hazards** Harmful if swallowed.

**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 None.

2.3. Other hazards Not assigned.

# **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

**General information** 

CAS-No. / EC No. REACH Registration No. INDEX No. Chemical name % **Notes** # Sodium azide 0.2 26628-22-8 011-004-00-7 247-852-1

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

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

**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** 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

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the

surrounding fire.

Unsuitable extinguishing

media

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.

<sup>#:</sup> This substance has been assigned Community workplace exposure limit(s).

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 at controlled room temperature at 15-30 °C (59-86°F). Store in a closed container away

from incompatible materials.

7.3. Specific end use(s) For in vitro diagnostic use.

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

## Occupational exposure limits

#### **UK. EH40 Workplace Exposure Limits (WELs)**

Components	Туре	Value	
Sodium azide (CAS 26628-22-8)	STEL	0.3 mg/m3	
20020-22-0)	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.

Not available. Derived no-effect level (DNEL)

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering

controls

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

shower.

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** Colourless liquid.

**Physical state** Liquid. **Form** Liquid.

Colour Colourless, clear. Odour Not available.

**Odour threshold** Not available. 7 approximately Melting point/freezing point Not available Initial boiling point and boiling Not available.

range

Not applicable. Flash point Not applicable. **Evaporation rate** Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

Not applicable. Vapour pressure Not applicable. Vapour density Relative density Not available. Soluble Solubility(ies) Not available. **Partition coefficient** 

(n-octanol/water)

**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 Stable at normal conditions.

10.2. Chemical stability Material is stable under normal conditions. 10.3. Possibility of hazardous Contact with acids liberates toxic gas.

reactions

10.4. Conditions to avoid Protect against direct sunlight.

10.5. Incompatible materials Strong oxidising agents. Acids. Heavy metals.

10.6. Hazardous None.

decomposition products

## **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 be harmful if swallowed.

Vapours may irritate throat and respiratory system and cause coughing. Inhalation

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.

May cause eye irritation on direct contact. **Symptoms** 

#### 11.1. Information on toxicological effects

May be harmful if swallowed. **Acute toxicity** 

**Test results** Components **Species** 

Sodium azide (CAS 26628-22-8)

**Acute** Dermal

LD50 Rabbit 20 mg/kg

Oral

LD50 Rat 27 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause redness, irritation and dry skin.

Serious eye damage/irritation Not classified. Respiratory sensitisation Not classified

Skin sensitisation Not classified. Germ cell mutagenicity Not classified. Not classified. Carcinogenicity Reproductive toxicity Not classified.

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

**Aspiration hazard** 

Mixture versus substance

information

Not classified. Not available.

Not available. Other information

## **SECTION 12: Ecological information**

Not expected to be harmful to aquatic organisms. 12.1. Toxicity

Components Species **Test results** 

Sodium azide (CAS 26628-22-8)

**Aquatic** 

EC50 Crustacea 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** Not available.

n-octanol/water (log Kow)

**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 Not available.

# **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Residual waste Dispose in accordance with all applicable regulations. Empty containers or liners may retain some

product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging

EU waste code

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

Waste codes should be assigned by the user based on the application for which the product was

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.

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

Not applicable.

# **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.

Additional information is given in the Safety Data Sheet.

National regulations The product has not been classified as dangerous according to the legislation in force.

15.2. Chemical safety

No Chemical Safety Assessment has been carried out.

assessment

## **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 Not available.

Information on evaluation method leading to the classification of mixture

Full text of any statements or R-phrases and H-statements under Sections 2 to 15 The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

R22 Harmful if swallowed. 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 Disclaimer

Not available.

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.

# MATERIAL SAFETY DATA SHEET



# 1. Product and Company Identification

Material name OSOM® Mono Test Positive Control, ImmunoCard STAT Mono Test Positive Control,

Sure-Vue Signature Mono Test Positive Control

Version # 01

**Issue date** 09-04-2012

Revision date Supersedes date -

CAS # Mixture

**Kit number** 145, 755725, 23-200-275

Product use Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For use in the qualitative detection

of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in

the diagnosis of infectious mononucleosis. For In Vitro Diagnostic Use Only.

Synonym(s) Mono CONTROL +

**Manufacturer information** 

Corporate Headquarters Sekisui Diagnostics, LLC

31 New York Avenue, Framingham, MA 01701 USA

www.sekisuidiagnostics.com

Phone: 800-332-1042 Americas 1-760-476-3962

**Emergency Telephone** 

**Numbers** 

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

#### 2. Hazards Identification

Physical state Liquid.

Appearance Clear. Colorless liquid.

**Emergency overview** Physical and health hazard information on reagent mixtures have not been determined.

OSHA regulatory status This product is not hazardous according to OSHA 29CFR 1910.1200.

Potential health effects

**Routes of exposure** Inhalation. Ingestion. Skin contact. Eye contact. **Eyes** Splashes may irritate and cause redness.

**Skin** Prolonged skin contact may cause redness, irritation and dry skin.

**Inhalation** Vapors and mist may irritate throat and respiratory system and cause coughing.

**Ingestion** May cause discomfort if swallowed.

Chronic effects No data available.

**Signs and symptoms** Ingestion may cause irritation and malaise.

Potential environmental 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.

## 3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

## 4. First Aid Measures

First aid procedures

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.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get

medical attention if irritation develops and persists.

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

OSOM® Mono Test Positive Control, ImmunoCard STAT Mono Test Positive Control, Sure-Vue Signature Mc
903103 Version #: 01 Revision date: - Issue date: 09-04-2012 1/5

**Ingestion** If material is ingested, immediately contact a poison control center.

**Notes to physician** Provide general supportive measures and treat symptomatically.

General advice Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves.

5. Fire Fighting Measures

Flammable properties This product is not flammable.

**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.

**Protection of firefighters** 

Specific hazards arising from the chemical

Protective equipment and

When heated to decomposition, may produce hydrazoic acid fumes.

precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.

**Hazardous combustion** 

products

Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide.

6. Accidental Release Measures

Personal precautions Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during

clean-up. Do not touch damaged containers or spilled material unless wearing appropriate

protective clothing.

**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.

**Methods for containment** 

Methods for cleaning up

Absorb spillage with non-combustible, absorbent material.

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.

Other information Clean up in accordance with all applicable regulations.

7. Handling and Storage

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.

Storage Store at controlled room temperature at 15–30 °C (59-86°F). Store in a closed container away

from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits No expo

No exposure limits noted for ingredient(s). Follow standard monitoring procedures.

Exposure guidelines
Engineering controls

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

shower.

Personal protective equipment

**Eye / face protection** Wear approved safety glasses or goggles.

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

Respiratory protection

Under normal conditions, respirator is not normally required.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance Clear. Colorless liquid.

Physical state Liquid.
Form Liquid.

Color Colorless, clear.

OSOM® Mono Test Positive Control, ImmunoCard STAT Mono Test Positive Control, Sure-Vue Signature Mo

CPH MSDS NA

Odor Not available. Odor threshold Not available. Ηq 7 approximate Vapor pressure Not available. Not available. Vapor density Not available. **Boiling point** Not available. Melting point/Freezing point Soluble Solubility (water)

Specific gravityNot available.Flash pointNot available.Flammability limits in air,Not available.

Flammability limits in air, upper, % by volume

Flammability limits in air,

**Auto-ignition temperature** 

Not available.

lower, % by volume

Not available.

# 10. Chemical Stability & Reactivity Information

**Chemical stability** Material is stable under normal conditions.

Conditions to avoid Protect against direct sunlight.

**Incompatible materials** Strong oxidizing agents. Acids. Heavy metals.

Hazardous decomposition

products

None.

Possibility of hazardous

reactions

Contact with acids liberates toxic gas.

# 11. Toxicological Information

**Sensitization** No data available.

Acute effects May cause discomfort if swallowed.

**Local effects** May cause eye irritation on direct contact.

Chronic effects No data available.

Carcinogenicity Not classified.

**Epidemiology** No epidemiological data is available for this product.

MutagenicityNot classified.Reproductive effectsNot classified.

**Symptoms and target organs** May cause eye irritation on direct contact.

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

# 12. Ecological Information

**Ecotoxicity** 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.

**Environmental effects**An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Aquatic toxicity Not classified.

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

Bioaccumulation / Accumulation

Not available.

Mobility in environmental

media

The product is soluble in water.

## 13. Disposal Considerations

**Disposal instructions**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.

Waste from residues / unused

products

Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging

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

# 14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

**TDG** 

Not regulated as dangerous goods.

# 15. Regulatory Information

**US federal regulations** This product is not hazardous according to OSHA 29CFR 1910.1200.

All components are on the U.S. EPA TSCA Inventory List.

This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug

Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A) Section 311/312 (40 CFR

No

No

370)

Drug Enforcement

Canadian regulations

Administration (DEA) (21 CFR

1308.11-15)

Not controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS

contains all the information required by the CPR.

WHMIS status Non-controlled

Inventory status

Country(s) or region Inventory name

On inventory (yes/no)\*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

**US. Massachusetts RTK - Substance List** 

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

OSOM® Mono Test Positive Control, ImmunoCard STAT Mono Test Positive Control, Sure-Vue Signature Mo

CPH MSDS NA

Yes

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard

(NOM-018-STPS-2000).

16. Other Information

**Recommended restrictions** Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 0

Flammability: 0 Physical hazard: 0

NFPA ratings Health: 0

Flammability: 0 Instability: 0

**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.

OSOM® Mono Test Positive Control, ImmunoCard STAT Mono Test Positive Control, Sure-Vue Signature Mo

CPH MSDS NA

903103 Version #: 01 Revision date: - Issue date: 09-04-2012

# **MATERIAL SAFETY DATA SHEET**



# 1. Product and Company Identification

Material name OSOM® Mono Test Negative Control, ImmunoCard STAT Mono Test Negative Control,

Sure-Vue Signature Mono Test Negative Control

Version # 01

**Issue date** 05-24-2013

Revision date - Supersedes date -

CAS # Mixture

**Kit number** 145, 755725, 23-200-275

Product use Component of OSOM® Mono Test kit (Catalog # 145 & 145E). For use in the qualitative detection

of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in

the diagnosis of infectious mononucleosis. For In Vitro Diagnostic Use Only.

Synonym(s) Mono CONTROL -

**Manufacturer information** 

Corporate Headquarters Sekisui Diagnostics, LLC

4 Hartwell Place, Lexington, MA 02421, USA

www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962

**Emergency Telephone** 

**Numbers** 

Europe, Middle East & Africa +1-760-476-3961

Asia Pacific +1-760-476-3960

Access code 333512

## 2. Hazards Identification

Physical state Liquid.

Appearance Clear. Colorless liquid.

Emergency overview CAUTION

May be harmful if swallowed. The chemical, physical and toxicological properties of this

preparation have not been thoroughly characterized.

OSHA regulatory status

Potential health effects

This product is hazardous according to OSHA 29 CFR 1910.1200.

**Routes of exposure** Inhalation. Ingestion. Skin contact. Eye contact. **Eyes** Splashes may irritate and cause redness.

**Skin** Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed

through the skin and result in systemic effects.

**Inhalation** Vapors and mist may irritate throat and respiratory system and cause coughing.

Ingestion May be harmful if swallowed. Do not ingest.

Signs and symptoms Ingestion may cause irritation and malaise.

Potential environmental effects Not expected to be harmful to aquatic organisms.

# 3. Composition / Information on Ingredients

Components	CAS#	Percent	
Sodium azide	26628-22-8	0.2	

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in

percent by volume.

OSOM® Mono Test Negative Control, ImmunoCard STAT Mono Test Negative Control, Sure-Vue Signature Mono Test Ne 903108 Version #: 01 Revision date: - Issue date: 05-24-2013

#### 4. First Aid Measures

First aid procedures

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.

Skin contact For skin contact flush with large amounts of water while removing contaminated clothing. Get

medical attention if irritation develops and persists.

Inhalation Move to fresh air. Call a physician if symptoms develop or persist. Ingestion If material is ingested, immediately contact a poison control center. Notes to physician Provide general supportive measures and treat symptomatically.

# 5. Fire Fighting Measures

Flammable properties This product is not flammable.

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.

**Protection of firefighters** 

Specific hazards arising from the chemical

Protective equipment and

precautions for firefighters

When heated to decomposition, may produce hydrazoic acid fumes.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

**Hazardous combustion** 

products

Use standard firefighting procedures and consider the hazards of other involved materials.

Fire will generate toxic and irritating gases. Carbon monoxide and carbon dioxide. Nitrogen oxides.

#### 6. Accidental Release Measures

Personal precautions Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during

clean-up. Do not touch damaged containers or spilled material unless wearing appropriate

protective clothing.

**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.

**Methods for containment** 

Absorb spillage with non-combustible, absorbent material.

Methods for 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.

Other information Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean

up in accordance with all applicable regulations.

## 7. Handling and Storage

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.

Store at controlled room temperature at 15-30 °C (59-86°F). Store in a closed container away from Storage

incompatible materials.

## 8. Exposure Controls / Personal Protection

## Occupational exposure limits

## **US. ACGIH Threshold Limit Values**

Components	Туре	Value	
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3	
		0.11 ppm	

## Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Туре	Value	Form	
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3	Vapor.	
		0.29 mg/m3		
		0.11 ppm	Vapor.	

# Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Туре	Value	Form
Sodium azide (CAS 26628-22-8)	Ceiling	0.29 mg/m3	
,		0.11 ppm	Vapor.

## Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Туре	Value	
Sodium azide (CAS	Ceiling	0.29 mg/m3	
26628-22-8)			

#### Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Туре	Value	
Sodium azide (CAS 26628-22-8)	Ceiling	0.3 mg/m3	
,		0.11 ppm	

**Exposure guidelines** Follow standard monitoring procedures.

US - California OELs: Skin designation

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

**US - Tennesse OELs: Skin designation** 

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

**US. NIOSH: Pocket Guide to Chemical Hazards** 

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

US. OSHA Table Z-1-A (29 CFR 1910.1000)

Sodium azide (CAS 26628-22-8)

Can be absorbed through the skin.

**Engineering controls** Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

shower.

Personal protective equipment

**Eye / face protection** Wear approved safety glasses or goggles.

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

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

**General hygiene** Handle in accordance with good industrial hygiene and safety practice. **considerations** 

# 9. Physical & Chemical Properties

Appearance Clear. Colorless liquid.

Physical state Liquid. Form Liquid.

Color Colorless, clear. Odor Not available. **Odor threshold** Not available. 7 Approximately Hq Vapor pressure Not available. Not available. Vapor density Not available. **Boiling point** Not available. Melting point/Freezing point Solubility (water) Soluble

Specific gravityNot available.Flash pointNot available.

Flammability limits in air, upper, % by volume

Not available.

Flammability limits in air,

lower, % by volume

Not available.

Auto-ignition temperature Not available.

# 10. Chemical Stability & Reactivity Information

**Chemical stability** Material is stable under normal conditions.

Conditions to avoid Protect against direct sunlight.

**Incompatible materials** Strong oxidizing agents. Acids. Heavy metals.

**Hazardous decomposition** 

products

None.

# 11. Toxicological Information

Toxicological data

Components Species Test Results

Sodium azide (CAS 26628-22-8)

**Acute** 

Dermal

LD50 Rabbit 20 mg/kg

Oral

LD50 Rat 27 mg/kg

Sensitization Not classified.

Acute effects May be harmful if swallowed.

**Local effects** May cause eye irritation on direct contact.

Chronic effects No data available.

Carcinogenicity Not classified.

**ACGIH Carcinogens** 

Sodium azide (CAS 26628-22-8)

A4 Not classifiable as a human carcinogen.

**Epidemiology** No epidemiological data is available for this product.

MutagenicityNot classified.Reproductive effectsNot classified.

Symptoms and target organs May cause eye irritation on direct contact.

# 12. Ecological Information

**Ecotoxicological data** 

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

**Ecotoxicity** No data available.

Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Aquatic toxicity Not classified.

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

Bioaccumulation /

Not available.

Accumulation

**Mobility in environmental** The product is soluble in water.

media

OSOM® Mono Test Negative Control, ImmunoCard STAT Mono Test Negative Control, Sure-Vue Signature Mono Test Negative Con

4/6

# 13. Disposal Considerations

Waste codes

US RCRA Hazardous Waste P List: Reference

Sodium azide (CAS 26628-22-8) P105

**Disposal instructions** 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.

Waste from residues / unused

products

Dispose in accordance with all applicable regulations. Empty containers or liners may retain some

product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

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

# 14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

**IATA** 

Not regulated as dangerous goods.

**IMDG** 

Not regulated as dangerous goods.

**TDG** 

Not regulated as dangerous goods.

# 15. Regulatory Information

**US** federal regulations This product is hazardous according to OSHA 29 CFR 1910.1200.

All components are on the U.S. EPA TSCA Inventory List.

This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug

Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Spill: Reportable quantity

Sodium azide (CAS 26628-22-8) 1000 lbs

US EPCRA (SARA Title III) Section 302 - Extremely Hazardous Substance: Threshold Planning Quantity

Sodium azide (CAS 26628-22-8)

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Sodium azide (CAS 26628-22-8)

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Sodium azide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - Yes

> Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)

No

SARA 311/312 Hazardous

No

chemical

**Drug Enforcement** 

Administration (DEA) (21 CFR

1308.11-15)

Not controlled

OSOM® Mono Test Negative Control, ImmunoCard STAT Mono Test Negative Control, Sure-Vue Signature Mono Test Ne 903108 Version #: 01 Revision date: - Issue date: 05-24-2013

**CPH MSDS NA** 

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS

contains all the information required by the CPR.

WHMIS status Non-controlled

#### Inventory status

Country(s) or region Inventory name On inventory (yes/no)\*

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

State regulations

This product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Sodium azide (CAS 26628-22-8)

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

US - New Jersey RTK - Substances: Listed substance

Sodium azide (CAS 26628-22-8) Listed.

**US. Massachusetts RTK - Substance List** 

Sodium azide (CAS 26628-22-8) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Sodium azide (CAS 26628-22-8) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Sodium azide (CAS 26628-22-8) Listed.

**Mexico regulations** This safety data sheet was prepared in accordance with the Official Mexican Standard

(NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

**Further information** HMIS® is a registered trade and service mark of the NPCA.

**HMIS®** ratings

Flammability: 0 Physical hazard: 0

NFPA ratings Health: 1

> Flammability: 0 Instability: 0

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.

OSOM® Mono Test Negative Control, ImmunoCard STAT Mono Test Negative Control, Sure-Vue Signature Mono Test Ne 903108 Version #: 01 Revision date: - Issue date: 05-24-2013

**CPH MSDS NA**