

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

· **Product identifier**

- **Trade name:** *ST HbA1c CALIBRATOR SET (025318): Concerned item: ST HbA1c CALIBRATOR (I)*
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** *In Vitro Diagnostics.*

· **Details of the supplier of the safety data sheet**

· **Manufacturer** / **Supplier:**

TOSOH CORPORATION
3-8-2 Shiba, Minato-ku
Tokyo 105 -8623
JAPAN

TOSOH BIOSCIENCE, INC.
6000 Shoreline Ct.; Suite 101
South San Francisco, CA94080
USA

Tel. : + 81 3 5427 5181

Phone : + 1 614 317 1909 or (800) 248 6764

Fax : + 81 3 5427 5220

Fax : + 1 877 898 9883 or (800) 685 7595

· **Information department:**

QA-RA: susan.koss@tosoh.com

www.diagnostics.us.tosohbioscience.com

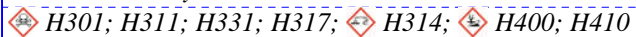
- **Emergency telephone number:** *Poison Control Center: + 1 800 222 1222*

2 Composition/information on ingredients

· **Chemical characterization:** *Mixtures*

- **Description:** *Mixture of the substances listed below with nonhazardous additions.*

· **Dangerous components:**

26172-55-4	5-chloro-2-methyl-2H-isothiazol-3-one	≤ 2.5%
		

3 Hazards identification

· **Classification of the substance or mixture**



H317 May cause an allergic skin reaction.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



May cause sensitisation by skin contact.

· **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.

· **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **Code letter and hazard designation of product:**



· **Hazard-determining components of labelling:**

5-chloro-2-methyl-2H-isothiazol-3-one

(Contd. on page 2)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/02/2011

Reviewed on 03/02/2011

Trade name: **ST HbA1c CALIBRATOR SET (0025318): Concerned item: ST HbA1c CALIBRATOR (1)**

(Contd. of page 1)

- **Risk phrases:**

May cause sensitisation by skin contact.

- **Safety phrases:**

Keep out of the reach of children.

Avoid contact with skin.

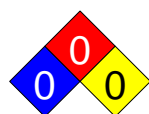
Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

Wear suitable gloves.

If swallowed, seek medical advice immediately and show this container or label.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

4 First aid measures

- **Description of first aid measures**

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **After swallowing:** If symptoms persist consult doctor.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **Special hazards arising from the substance or mixture** No further relevant information available.

- **Advice for firefighters**

- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.

- **Environmental precautions:**

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

(Contd. on page 3)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/02/2011

Reviewed on 03/02/2011

Trade name: **ST HbA1c CALIBRATOR SET (0025318): Concerned item: ST HbA1c CALIBRATOR (1)**

(Contd. of page 2)

- Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

(Contd. on page 4)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/02/2011

Reviewed on 03/02/2011

Trade name: ST HbA1c CALIBRATOR SET (0025318): Concerned item: ST HbA1c CALIBRATOR (1)

(Contd. of page 3)

- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Goggles recommended during refilling.

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Fluid
Color:	Colorless
Odor:	Odorless
Odour threshold:	Not determined.

· **pH-value at 20°C (68°F):** 4.4

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· Ignition temperature:

Decomposition temperature: Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· Solubility in / Miscibility with

Water: Fully miscible.

· **Segregation coefficient (n-octanol/water):** Not determined.

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

· Solvent content:

Organic solvents: 0.0 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· Reactivity

· Chemical stability

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

(Contd. on page 5)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/02/2011

Reviewed on 03/02/2011

Trade name: ST HbA1c CALIBRATOR SET (0025318): Concerned item: ST HbA1c CALIBRATOR (1)

(Contd. of page 4)

· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **DOT regulations:**

· **Hazard class:** -

· **Land transport ADR/RID (cross-border):**

· **ADR/RID class:** -

· **Maritime transport IMDG:**

· **IMDG Class:** -

· **Marine pollutant:** No

· **Air transport ICAO-TI and IATA-DGR:**

· **ICAO/IATA Class:** -

(Contd. on page 6)

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 03/02/2011

Reviewed on 03/02/2011

Trade name: ST HbA1c CALIBRATOR SET (0025318): Concerned item: ST HbA1c CALIBRATOR (1)

(Contd. of page 5)

- **UN "Model Regulation":** -
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

- **Hazard symbols:**



Irritant

- **Hazard-determining components of labelling:**

5-chloro-2-methyl-2H-isothiazol-3-one

- **Risk phrases:**

May cause sensitisation by skin contact.

(Contd. on page 7)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 03/02/2011

Reviewed on 03/02/2011

Trade name: ST HbA1c CALIBRATOR SET (0025318): Concerned item: ST HbA1c CALIBRATOR (1)

(Contd. of page 6)

· Safety phrases:*Keep out of the reach of children.**Avoid contact with skin.**Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.**Wear suitable gloves.**If swallowed, seek medical advice immediately and show this container or label.***· Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

USA