

**TOSOH BIOSCIENCE****SAFETY DATA SHEET****HbA1c Calibrator Set (S)**

This safety data sheet was created pursuant to the requirements of:  
US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200)

**1. Identification****Product identifier**

**Product Name** HbA1c Calibrator Set (S)

**Other means of identification**

**Safety data sheet number** 0000248

**Product Code(s)** HbA1c Calibrator Set (S) PN 0023502

**Synonyms** None

**Recommended use of the chemical and restrictions on use**

**Recommended use** This product is used with the specified in-vitro diagnostic medical equipment (Tosoh Automated Glycohemoglobin Analyzer HLC-723G8, G9, GX, G11, GR01)

**Restrictions on use** Any use other than the recommended use is prohibited.

**Details of the supplier of the safety data sheet****Supplier Address**

Tosoh Bioscience, Inc.  
3600 Gantz Road  
Grove City, OH 43123  
Tel: +1-800-248-6764

**E-mail address** info.diag.am@tosoh.com

**Emergency telephone number**

**Company Phone Number** +1-800-248-6764

**Emergency Telephone** No information available

**2. Hazard(s) identification****Classification of the substance or mixture**

This product is not considered hazardous by the US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200).

**Hazards not otherwise classified (HNOC)**

Not applicable.

**Label elements****Signal word**

Not applicable

**Hazard statements**

No hazard statements required

**Precautionary Statements - Prevention**

Not applicable

**Precautionary Statements - Response**

Not applicable

**Precautionary Statements - Storage**

Not applicable

**Precautionary Statements - Disposal**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

No information available.

**Other information**

No information available.

**3. Composition/information on ingredients****Substance**

Not applicable.

**Mixture****Common name** Hemoglobin.

Chemical name	CAS No.	Weight-%	Trade secret
Hemoglobin (human origin)	9008-02-0	90-99%	Not applicable

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

Trade Secret Statement

For CAS numbers listed as "trade secret", specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

**4. First-aid measures****Description of first aid measures**

<b>General advice</b>	Take a copy of the Safety Data Sheet when going for medical treatment.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Rinse mouth.

**Self-protection of the first aider** Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. First aid personnel should wear protective equipment such as rubber gloves and sealed goggles.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** No information available.

**Effects of Exposure** No information available.

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

**Note to physicians** Treat symptomatically. Handle this product as infectious material.

## 5. Fire-fighting measures

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical powder, foam, carbon dioxide, dry sand, water spray.

**Small Fire** Dry chemical powder, foam, carbon dioxide, dry sand, water spray.  
**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical** No information available.

**Hazardous combustion products** No information available.

**Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Ensure adequate ventilation. Wear protective gloves/clothing and eye/face protection. Do not breathe dust.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

**Prevention of secondary hazards** No information available.

## 7. Handling and storage

**Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice. Wash hands thoroughly after handling.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Store at 2-8°C to prevent water damage.

**Packaging materials** Use sealed vial bottles, stainless steel, or plastic containers.

**8. Exposure controls/personal protection**

**Control Parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Safety glasses with side shields are recommended for medical or industrial exposures.

**Hand protection** Wear suitable gloves.

**Skin and body protection** No special protective equipment required.

**Respiratory protection** When respirators are required, select NIOSH/MSHA approved equipment based on actual or potential airborne concentrations and in accordance with regulatory standards and/or industrial recommendations.

**Environmental exposure controls** Prevent product from entering drains. Do not allow into any sewer, on the ground or into any body of water.

**Thermal hazards** None under normal processing.

**9. Physical and chemical properties**

**Information on basic physical and chemical properties**

**Appearance** Solid (lumps)  
**Physical state** Solid  
**Color** Brown  
**Odor (includes odor threshold)** No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point (or initial boiling point or boiling range)</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>	No data available	None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>	No data available	None known
<b>SADT (°C)</b>	No data available	None known

pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Solubility	No data available	None known
Water solubility	No data available	None known
Partition coefficient n-octanol/water (log value)	No data available	None known
Vapor pressure (includes evaporation rate)	No data available	None known
Evaporation rate	No data available	None known
Density and/or relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		None known
Particle Size	No data available	
Particle Size Distribution	No data available	
<b><u>Other information</u></b>		
Molecular formula	No information available	
Molecular weight	No information available	
VOC content	No information available	

## 10. Stability and reactivity

Reactivity	Poor reactivity.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Hazardous polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

Product Information	Though human-derived components passed test and has been used, treat as infectious material.
Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Acute toxicity No information available.

**Numerical measures of toxicity**

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

## **12. Ecological information**

Ecotoxicity No information available.

Persistence and degradability No information available.

Bioaccumulative potential No information available.

Mobility in soil No information available.

Other adverse effects No information available.

Ozone depletion potential (ODP) No information available

Endocrine disrupting properties This product does not contain any known or suspected endocrine disruptors.

## **13. Disposal considerations**

**Disposal methods**

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

## **14. Transport information**

Note: This material is not subject to regulation as a hazardous material for shipping

DOT Not regulated

**IATA** Not regulated

**IMDG** Not regulated

## 15. Regulatory information

### International Regulations

**The Montreal Protocol on Substances that Deplete the Ozone Layer** Not applicable

**The Stockholm Convention on Persistent Organic Pollutants** Not applicable

**The Rotterdam Convention** Not applicable

### International Inventories

**TSCA** All ingredients are listed or exempt.

Chemical name	CAS No.	Inventory Listing Status	Commercial Activity Designation
Hemoglobin (human origin)	9008-02-0	Present	Active

**DSL/NDSL** Contact supplier for inventory compliance status.  
**EINECS/ELINCS** Contact supplier for inventory compliance status.  
**ENCS** Contact supplier for inventory compliance status.  
**IECSC** Contact supplier for inventory compliance status.  
**KECL** Contact supplier for inventory compliance status.  
**PICCS** Contact supplier for inventory compliance status.  
**AIIC** Contact supplier for inventory compliance status.  
**NZIoC** Contact supplier for inventory compliance status.  
**TCSI** Contact supplier for inventory compliance status.

#### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AIIC** - Australian Inventory of Industrial Chemicals

**NZIoC** - New Zealand Inventory of Chemicals

**TCSI** - Taiwan Chemical Substance Inventory

### US Federal Regulations

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CAA (Clean Air Act)**

This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information**

<b><u>NFPA</u></b>	<b>Health hazards</b> 0	<b>Flammability</b> 0	<b>Instability</b> 0	<b>Special hazards</b> -
<b><u>HMIS</u></b>	<b>Health hazards</b> 0	<b>Flammability</b> 0	<b>Physical hazards</b> 0	<b>Personal protection</b> -

**Key or legend to abbreviations and acronyms used in the safety data sheet**

List may include phrases which are not applicable to this product

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
GHS	Globally Harmonized System
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ICAO	International Civil Aviation Organization
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Organization for Standardization
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)



MARPOL	International Convention for the Prevention of Pollution from Ships
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NTP	National Toxicology Program (United States)
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
OSHA	Occupational Safety and Health Administration of the US Department of Labor
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
As	Allergenic substance
DS	Dermal Sensitizer
Ot	Ototoxicant
pOt	Ototoxicant - potential to cause hearing disorders
PS	Photosensitizer
RS	Respiratory Sensitizer
S	Sensitizer
poS	Sensitizer - capable of causing occupational asthma
Sa	Simple asphyxiant
Sd	Skin designation
pSd	Skin designation - potential for cutaneous absorption
Sdv	Skin designation - vacated
Sk	Skin notation
dSk	Skin notation - danger of cutaneous absorption
pSk	Skin notation - potential for cutaneous absorption

**Key literature references and sources for data used to compile the SDS**

U.S. Agency for Toxic Substances and Disease Registry (ATSDR)  
 U.S. Environmental Protection Agency ChemView Database  
 European Food Safety Authority (EFSA)  
 U.S. Environmental Protection Agency  
 Acute Exposure Guideline Level(s) (AELG(s))  
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
 U.S. Environmental Protection Agency High Production Volume Chemicals  
 Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan National Institute of Technology and Evaluation (NITE)

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

International Organization for Economic Co-operation and Development (OECD) Environment, Health, and Safety Publications

International Organization for Economic Co-operation and Development (OECD) High Production Volume Chemicals Program

International Organization for Economic Co-operation and Development (OECD) Screening Information Data Set

United Nations World Health Organization (WHO)

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<b>Revision Note</b>	Original version.

#### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**