

**TOSOH BIOSCIENCE****SAFETY DATA SHEET****Hemoglobin A1c Control Set**

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 Hemoglobin A1c Control Set

Other means of identification

Safety data sheet number 0000249

Product Code(s) Hemoglobin A1c Control Set PN 0018767

Synonyms Blood products (lyophilized)

Recommended use of the chemical and restrictions on use

Recommended use This product is used for specified in vitro diagnostic medical equipment

Restrictions on use Use for purposes 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****Common name**

Freeze-dried hemolyzed blood containing stabilizers.

Synonyms

Blood products (lyophilized)

Chemical name	CAS No.	Weight-%	Trade secret
Freeze-dried hemolyzed blood containing stabilizers	Not available	≥ 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****General advice**

Take a copy of the Safety Data Sheet when going for medical treatment.

Inhalation

Remove to fresh air.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. Remove contact lenses, if present and easy to do. Continue rinsing.

Skin contact

Wash skin with soap and water.

Ingestion

Call a physician immediately. 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. Wear personal protective clothing (see section 8).
---	---

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, sand.
Small Fire	Dry chemical powder, foam, carbon dioxide, sand.
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. Fight fire from upwind side. If containers cannot be removed, spray water onto them and the surrounding area to cool down.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Personal precautions	Ensure adequate ventilation. Use personal protective equipment as required. Keep people away from and upwind of spill/leak.
For emergency responders	Use personal protection recommended in Section 8.

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	Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. Wash contaminated surfaces with plenty of water and 1% aqueous solution of sodium hypochlorite.
Prevention of secondary hazards	Remove all sources of ignition.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Wear suitable protective clothing, gloves, footwear, and/or eye protection.
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 in a dry, cool and well-ventilated place. Store at 2-8°C to prevent water damage.
Packaging materials	Appropriate containers and packaging materials.

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	Wear suitable protective clothing.
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	Powder
Physical state	Solid
Color	Brown
Odor (includes odor threshold)	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Boiling point (or initial boiling point or boiling range)	No data available	None known
Flammability	No data available	None known

Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
SADT (°C)	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	1.1	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	
Other information		
Molecular formula	No information available	
Molecular weight	No information available	
VOC content	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
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.

Acute toxicity No information available.

Numerical measures of toxicity

No information available

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 Contact supplier for inventory compliance status.

Chemical name	CAS No.	Inventory Listing Status	Commercial Activity Designation
Freeze-dried hemolyzed blood containing stabilizers	Not available	*	*

*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

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

NFPA	Health hazards 0	Flammability 0	Instability 0	Special hazards -
HMIS	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection -

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) (AEGl(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)

Issuing Date	03/13/2026
Revision date	03/13/2026
Revision Note	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