

Safety Data Sheet (HPLC 05)

acc. to OSHA HCS

Printing date 10/19/2015

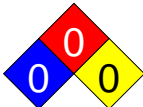
Reviewed on 10/19/2015

1: Identification

- **1.1 Product identifier**
- **Trade name:** Hemoglobin A1c Control Set, Levels 1 and 2
- **Article number:** 220232
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** In Vitro Diagnostics.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer / Supplier:**

Canterbury Scientific Ltd 71 Whiteleigh Avenue Addington Christchurch, 8011 NEW ZEALAND Phone : + 64 3 343 3345 Fax : + 64 3 343 3342	TOSOH BIOSCIENCE, INC. 6000 Shoreline Ct.; Suite 101 South San Francisco, CA94080 USA Phone : + 1 614 317 1909 or (800) 248 6764 Fax : + 1 877 898 9883 or (800) 685 759
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- **Information department:**
QA-RA: susan.koss@tosoh.com www.diagnostics.us.tosohbioscience.com
- **1.4 Emergency telephone number:** Poison Control Center: + 1 800 222 1222

2: Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**


Health = 0
Fire = 0
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3: Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.
- **Dangerous components:** Void

4: First-aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.

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- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**
No dangerous substances are released.
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

- **7.1 Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **7.2 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.
- **7.3 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.
- **8.1 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.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The human material, from which this product has derived, is from controlled voluntary donors.
The donors are tested negative for HBs antigen, HCV-, HIV-I – and HIV-II antibodies by approved tests.
No test method can offer complete assurance that products containing human material will be absent of these and of other infectious agents.
Normal laboratory precautions should be taken as for potential infectious material.

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Should be handled as an ordinary patient sample.
The use of disposable gloves is recommended.

- **Breathing equipment:** Not required.
- **Protection of hands:**
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.
- **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:** Not required.

9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Spray dried powder

Color: Dark red

· **Odor:** Odorless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **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 applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

Water: Soluble.

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

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **Solvent content:**

Organic solvents: 0.0 %

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Solids content: 100.0 %
9.2 Other information No further relevant information available.

10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
 The product is not subject to classification according to internally approved calculation methods for preparations:
 When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
56-75-7	chloramphenicol	2A

· NTP (National Toxicology Program)		
56-75-7	chloramphenicol	R

· OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients is listed.		

12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Smaller quantities can be disposed of with household waste.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14: Transport information

- | | |
|--|-----------------|
| <ul style="list-style-type: none"> · 14.1 UN-Number · DOT, ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · DOT, ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · DOT, ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | - |

15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Sara**
- | | |
|--|--|
| <ul style="list-style-type: none"> · Section 355 (extremely hazardous substances): | 151-50-8 potassium cyanide |
| <ul style="list-style-type: none"> · Section 313 (Specific toxic chemical listings): | 151-50-8 potassium cyanide |
| <ul style="list-style-type: none"> · TSCA (Toxic Substances Control Act): | All ingredients are listed. |
| <ul style="list-style-type: none"> · Proposition 65 | |
| <ul style="list-style-type: none"> · Chemicals known to cause cancer: | None of the ingredients is listed. |
| <ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for females: | None of the ingredients is listed. |
| <ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for males: | 151-50-8 potassium cyanide |
| <ul style="list-style-type: none"> · Chemicals known to cause developmental toxicity: | None of the ingredients is listed. |
| <ul style="list-style-type: none"> · Carcinogenic categories | |
| <ul style="list-style-type: none"> · EPA (Environmental Protection Agency) | 151-50-8 potassium cyanide II |
| <ul style="list-style-type: none"> · TLV (Threshold Limit Value established by ACGIH) | None of the ingredients is listed. |

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

None of the ingredients is listed.

· **Labelling according to Regulation (EC) No 1272/2008** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **15.2 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.

The information contained herein is prepared based on the available information to Tosoh that is believed to be reliable; however the information is provided by Tosoh WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO ITS COMPLETENESS, COMPREHENSIVENESS AND ACCURACY.

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When the revision of this SDS is received, please dispose of the old one.

· **Date of preparation / last revision** 10/19/2015 / -

· **Abbreviations and acronyms:**

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

ICAO: International Civil Aviation Organisation

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

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)