

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

· **Product identifier**

· **Trade name:** Hemoglobin F and A2 Control

· **Article number:** 997050

· **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:**

Canterbury Scientific Ltd
71 Whiteleigh Avenue
Addington
Christchurch, 8011
NEW ZEALAND

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

USA

Phone : + 64 3 343 3345

Fax : + 64 3 343 3342

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

Fax : + 1 877 898 9883 or (800) 685 759

· **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:** *Void*

3 Hazards identification

· **Classification of the substance or mixture**

The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** *Not applicable.*

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

The product does not have 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:**

Observe the general safety regulations when handling chemicals.

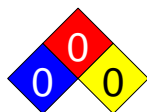
The product is not subject to identification regulations according to directives on hazardous materials.

· **Safety phrases:**

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

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- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

4 First aid measures

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

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **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.

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.

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· **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.

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

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

· **General Information**

· **Appearance:**

Form: Spray dried powder

Color: Dark red

· **Odor:** Odorless

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

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

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

· **Density:** Not determined.

· **Solubility in / Miscibility with**

Water: Fully miscible.

· **Solvent content:**

Organic solvents: 0.0 %

Solids content: 100.0 %

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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.
- **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:** 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.

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** 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.

13 Disposal considerations

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

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- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **UN "Model Regulation":** -
- **Special precautions for user** Not applicable.

15 Regulatory information

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

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

151-50-8 | potassium cyanide

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

151-50-8 | potassium cyanide

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

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

56-75-7 | chloramphenicol

· **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)**

56-75-7 | chloramphenicol

2A

· **NTP (National Toxicology Program)**

56-75-7 | chloramphenicol

R

· **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:**

Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations according to directives on hazardous materials.

· **Safety phrases:**

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

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

Material Safety Data Sheet

acc. to ISO/DIS 11014

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Reviewed on 02/03/2011

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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