

HbA1c Calibrators and Controls

Date 14.9.2007

Previous date: 10.6.2005

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**1.1 Identification of the article****1.1.1 Commercial Product Name**

HbA1c Calibrators and Controls

1.1.2 Product code

981658, 981695, 981696

1.2 Use of the Substance/Preparation**1.2.1 Expressed in writing**

In vitro diagnostic calibrator/control for the clinical chemistry analyser.

1.3 Identification of the substance/preparation and the company/undertaking**1.3.1 Supplier**

Thermo Fisher Scientific Oy, Clinical Diagnostics Finland

1.3.2 Contact information:

Ratastie 2, P.O.Box 100
FI-01621 Vantaa
FINLAND
+358-9-329 100
+358-9-3291 0300
FI09215470

2. COMPOSITION/INFORMATION ON INGREDIENTS**2.1 Hazardous components**

2.1.1	2.1.2	2.1.3	2.1.4
CAS number or other code	Chemical name of the substance	Concentration	Classification
1119-97-7	Tetradecyltrimethyl-ammoniumbromide	7.7 %	C; R34

2.1.7 Further information

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3. HAZARDS IDENTIFICATION

Irritating to eyes and skin.

4. FIRST AID MEASURES**4.1 Additional advice**

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4.2 Inhalation

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4.3 Skin contact

Wash off immediately with plenty of water. Treat the contacted skin with skin-disinfectant.

4.4 Eye contact

Rinse immediately with plenty of water for at least 15 minutes.

4.5 Ingestion

Consult a physician.

5. FIRE-FIGHTING MEASURES

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5.1 Suitable extinguishing media
Water, foam, carbon dioxide (CO₂).

5.3 Specific hazards

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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions

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6.2 Environmental precautions

-

6.3 Methods for cleaning up

Sweep up in dry condition, avoiding dust formation.

7. HANDLING AND STORAGE

7.1 Handling

Combustible substance.

Avoid contact with skin and eyes.

7.2 Storage

Keep at temperatures between 2 and 8 °C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.2 Exposure controls

8.2.1 Occupational exposure controls

Handle in accordance with good industrial hygiene and safety practice. Disinfect workplace and hands after work.

8.2.1.1 Respiratory protection

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8.2.1.2 Hand protection

Protective gloves.

8.2.1.3 Eye protection

Safety glasses.

8.2.1.4 Skin and body protection

Lab coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General Information (appearance, odour)

Solid, odourless.

9.2 Important Health Safety and Environmental Information

9.2.1 pH 7.2

9.2.2 Boiling point/range -

9.2.3 Flash point -

9.2.5 Explosive properties -

9.2.5.1 Lower explosion limit -

9.2.5.2 Upper explosion limit -

9.2.7 Vapour pressure -

9.2.8 Relative density -

9.2.9 Solubility -

9.2.9.1 Water solubility completely soluble

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- 9.2.9.2** Fat solubility (solvent - oil to be specified) -
9.2.10 Partition coefficient (n-octanol/water) -
9.2.11 Viscosity -

10. STABILITY AND REACTIVITY

- 10.3** Hazardous decomposition products
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11. TOXICOLOGICAL INFORMATION

- 11.1** Acute toxicity
Tetradecyltrimethylammoniumbromide:
LD50/intravenous/rat =15 mg/kg
- 11.2** Primary irritation
Irritating to eyes and skin.
- 11.3** Sensitisation
-
- 11.5** Human experience
-

12. ECOLOGICAL INFORMATION

- 12.1** Ecotoxicity
- 12.1.1** Aquatic toxicity
-
- 12.1.2** Toxicity to other organisms
-
- 12.2** Mobility
-
- 12.3** Persistence and degradability
- 12.3.1** Biodegradation
-
- 12.3.2** Chemical degradation
-
- 12.4** Bioaccumulative potential
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13. DISPOSAL CONSIDERATIONS

The product has to be disposed of as laboratory chemical in accordance with local regulations.

14. TRANSPORT INFORMATION

- 14.1** UN-No -
- 14.3** Land transport
- 14.3.1** Class -
- 14.4** Sea transport
- 14.4.1** IMDG -
- 14.5** Air transport
- 14.5.1** ICAO/IATA -

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15. REGULATORY INFORMATION**15.1 Information on the warning label****EC Label****15.1.1 Letter code of the warning symbol and indications of danger for the preparation**

Xi Irritant

15.1.2 Names of the ingredients given on the warning label

Tetradecyltrimethylammoniumbromide

15.1.3 R-phrases(s)

R36/38 Irritating to eyes and skin.

15.1.4 S-phrases(s)

S24/25 Avoid contact with skin and eyes.

16. OTHER INFORMATION**16.1 List of the relevant R phrases**

R36/38 Irritating to eyes and skin.

R34 Causes burns.

16.4 Additional information available from:

Code of the Material Safety Data Sheet: D01585-05-05-MSDS-HbA1c Calibrators and Controls-EN
Corporation mentioned in point 1.3.

The information in this datasheet is to our best knowledge correct and complete, and is offered in good faith as accurate. It characterizes the product with regard to the appropriate safety precautions. It does not guarantee properties of the product.

16.5 Literary reference

The MSDS of the manufacturer.

This product has been evaluated in accordance with the directives 1967/548/EEC, 1999/45/EC and 2001/58/EC.

16.6 Additions, Deletions, Revisions

Changes in the sections 1.3.

Date

14.09.2007

Signature

LMKo