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Zone Industrielle
61500 Sées
France
Tel: +33 (0)2 33 81 21 00
Fax: +33 (0)2 33 28 77 51
www.elitechgroup.com

IMPORTANT INFORMATION CONCERNING MATERIAL SAFETY DATA SHEET / SAFETY DATA SHEET

Cher client,

Le 1^{er} Janvier 2013, le nom notre société SEPPIM S.A.S. change pour devenir ELITech Clinical Systems SAS. Toute notre documentation est en cours de révision pour prendre en compte ce changement de nom. Ceci inclut les Fiches de Données de Sécurité (FDS) fournies pour nos réactifs.

Les renseignements suivants de nos FDS sont modifiés à partir du 1^{er} Janvier 2013 comme indiqué ci-après:

Producteur/fournisseur :

ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées
France
Tel: +33 (0)2 33 81 21 00
Fax : +33 (0)2 33 28 77 51
MSDS.ECS-SAS@elitechgroup.com

Dear customer,

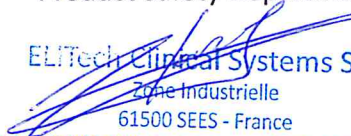
On 1st January 2013, the manufacturing company SEPPIM S.A.S. name changes to ELITech Clinical Systems SAS. All the documentation is in revision in light of the change of our company name. This includes the (Material) Safety Data Sheets ((M)SDSs) provided for our reagents.

The following contact information relative to (M)SDSs are modified from 1st January 2013 as indicated hereafter :

Manufacturer/Supplier :

ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées
France
Tel: +33 (0)2 33 81 21 00
Fax : +33 (0)2 33 28 77 51
MSDS.ECS-SAS@elitechgroup.com

Product Safety Department


ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

10.04.2012

Kit Components

Product code	Description
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HBAC-0049	HbA1c CONTROL L+H (Kit)
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Components:

HBAC-4605	HbA1c - CONTROL L
HBAC-4705	HbA1c - CONTROL H

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

- **Product identifier**
- **Trade name:** HbA1c - CONTROL L
- **Article number:** HBAC-4605
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
SEPPIM S.A.S.
4 Rue Auguste Mottin
F-61500 Sées
FRANCE
Tel: +33 2 33 81 21 00
Fax: +33 2 33 28 77 51
seppim.msds@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Lyophilised hemolysate prepared from human erythrocytes, containing stabilizers.
- **Dangerous components:**
Each of the components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).
- **Additional information:** Contains human sourced and/or potentially infectious components.

3 Hazards identification

- **Classification of the substance or mixture**
- **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.
- **Additional information:**
Contains human sourced and/or potentially infectious components.
Each human donor's blood unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.
Since, nevertheless, risk of infection cannot be fully precluded the product must be handled as potentially infectious.

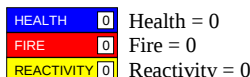
Label elements

- **Labelling according to EU guidelines:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals and/or products potentially infectious.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Clean with a disinfectant.
If symptoms appear, seek medical advice.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Never give anything by mouth to an unconscious person.
Rinse out mouth.
Seek advice from a doctor or a poison control center.

Material Safety Data Sheet

acc. to ISO/DIS 11014

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Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL L

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Firefighting measures

- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** Formation of toxic gases is possible during heating or in case of fire.
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Handle as potentially infectious.
Avoid formation of dust.
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully; suitable cleaners are:
Warm water and cleansing agent
Disinfectant.
- **Reference to other sections**
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

- **Handling:**
- **Precautions for safe handling**
Handle as potentially infectious.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **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:** Protect the product from light. Avoid exposure to heat.
- **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** Eyewash fountain and safety shower in the area of storage and use.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling products potentially infectious.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**
Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL L

(Contd. of page 2)

Protection of hands:



Protective gloves

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.

Material of gloves

Latex or rubber.

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:

Safety glasses

Body protection:

Protective work clothing

9 Physical and chemical properties

General Information

Appearance:

Form:

Freeze dried powder

Color:

Dark red

Odor:

Odorless

pH-value:

Not applicable

Change in condition

Melting point/Melting range:

Date not available

Boiling point/Boiling range:

Date not available

Flash point:

Date not available

Ignition temperature:

Date not available

Decomposition temperature:

Date not available

Auto igniting:

Product is not selfigniting.

Danger of explosion:

Product does not present an explosion hazard.

Vapor pressure:

Not applicable

Density:

Not applicable

Vapour density

Not applicable

Evaporation rate

Not applicable

Solubility in / Miscibility with

Water:

Fully miscible.

Segregation coefficient (n-octanol/water):

Not determined.

Viscosity:

Dynamic:

Not applicable

Kinematic:

Not applicable

Other information

No further relevant information available.

10 Stability and reactivity

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Incompatible materials: Strong oxidizing agents, acids, bases.

Hazardous decomposition products: Dangerous decomposition products may be formed.

Additional information: Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

Acute toxicity:

LD/LC50 values that are relevant for classification: Date not available

Primary irritant effect:

on the skin: May cause irritating effect.

on the eye: May cause irritating effect.

Inhalation:

May cause irritating effect.

May be harmful by inhalation.

Ingestion: May be harmful if swallowed.

(Contd. on page 4)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL L

(Contd. of page 3)

- **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.
Each human donor's blood unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.
Since, nevertheless, risk of infection cannot be fully precluded the product must be handled as potentially infectious.

12 Ecological information

- **Aquatic toxicity:** At present there are no ecotoxicological assessments.
- **Persistence and degradability** Date not available
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Date not 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.
Disposal procedures have to be respected, see Section 13.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:**
Water, if necessary with cleansing agents.
Disinfectant.
- **Primary packaging:** Glass bottle

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** -
- **UN proper shipping name**
- **DOT, ADN, IMDG, IATA** -
- **ADR** -
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** -
- **Packing group**
- **DOT, ADR, IMDG, IATA** -
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **SARA**
- **Section 302/304 (40CFR355.30 / 40CFR355.40):** Available information lists none.
- **Section 313 (Specific toxic chemical listings):** Not regulated.
- **TSCA (Toxic Substances Control Act):**
This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- **Proposition 65**
- **Chemicals known to cause cancer:** Available information lists none.
- **Chemicals known to cause reproductive toxicity for females:** Available information lists none.
- **Chemicals known to cause reproductive toxicity for males:** Available information lists none.
- **Chemicals known to cause developmental toxicity:** Available information lists none.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** None of the ingredient is listed.
- **IARC (International Agency for Research on Cancer)** Available information lists none.
- **NTP (National Toxicology Program)** Available information lists none.
- **TLV (Threshold Limit Value established by ACGIH)** Available information lists none.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Available information lists none.

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USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL L

(Contd. of page 4)

- *OSHA-Ca (Occupational Safety & Health Administration)* Available information lists none.
- **Product related hazard informations:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals and/or products potentially infectious.
- **U. S. State Regulations:**
- *PA-RTK* Available information lists none.
- *NJ-RTK* Available information lists none.
- *MA-RTK* Available information lists none.
- *RI-RTK* Available information lists none.

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.

- **Department issuing MSDS:** Product safety department
- **Contact:** Product safety department
- * *Data compared to the previous version altered.*

USA

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

- **Product identifier**
- **Trade name:** HbA1c - CONTROL H
- **Article number:** HBAC-4705
- **Application of the substance / the preparation** Reagent for IN VITRO diagnostic
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
SEPPIM S.A.S.
4 Rue Auguste Mottin
F-61500 Sées
FRANCE
Tel: +33 2 33 81 21 00
Fax: +33 2 33 28 77 51
seppim.msds@elitechgroup.com
- **Information department:** Product safety department
- **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Lyophilised hemolysate prepared from human erythrocytes, containing stabilizers.
- **Dangerous components:**
Each of the components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).
- **Additional information:** Contains human sourced and/or potentially infectious components.

3 Hazards identification

- **Classification of the substance or mixture**
- **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.
- **Additional information:**
Contains human sourced and/or potentially infectious components.
Each human donor's blood unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.
Since, nevertheless, risk of infection cannot be fully precluded the product must be handled as potentially infectious.

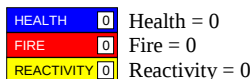
Label elements

- **Labelling according to EU guidelines:**
The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals and/or products potentially infectious.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



4 First aid measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Clean with a disinfectant.
If symptoms appear, seek medical advice.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Never give anything by mouth to an unconscious person.
Rinse out mouth.
Seek advice from a doctor or a poison control center.

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL H

(Contd. of page 1)

- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Firefighting measures

- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** Formation of toxic gases is possible during heating or in case of fire.
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Handle as potentially infectious.
Avoid formation of dust.
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully; suitable cleaners are:
Warm water and cleansing agent
Disinfectant.
- **Reference to other sections**
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

- **Handling:**
- **Precautions for safe handling**
Handle as potentially infectious.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **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:** Protect the product from light. Avoid exposure to heat.
- **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** Eyewash fountain and safety shower in the area of storage and use.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling products potentially infectious.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**
Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

(Contd. on page 3)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL H

(Contd. of page 2)

Protection of hands:



Protective gloves

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.

Material of gloves

Latex or rubber.

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:

Safety glasses

Body protection:

Protective work clothing

9 Physical and chemical properties

General Information

Appearance:

Form:

Freeze dried powder

Color:

Dark red

Odor:

Odorless

pH-value:

Not applicable

Change in condition

Melting point/Melting range:

Date not available

Boiling point/Boiling range:

Date not available

Flash point:

Date not available

Ignition temperature:

Date not available

Decomposition temperature:

Date not available

Auto igniting:

Product is not selfigniting.

Danger of explosion:

Product does not present an explosion hazard.

Vapor pressure:

Not applicable

Density:

Not applicable

Vapour density

Not applicable

Evaporation rate

Not applicable

Solubility in / Miscibility with

Water:

Fully miscible.

Segregation coefficient (n-octanol/water):

Not determined.

Viscosity:

Dynamic:

Not applicable

Kinematic:

Not applicable

Other information

No further relevant information available.

10 Stability and reactivity

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Incompatible materials: Strong oxidizing agents, acids, bases.

Hazardous decomposition products: Dangerous decomposition products may be formed.

Additional information: Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

Acute toxicity:

LD/LC50 values that are relevant for classification: Date not available

Primary irritant effect:

on the skin: May cause irritating effect.

on the eye: May cause irritating effect.

Inhalation:

May cause irritating effect.

May be harmful by inhalation.

Ingestion: May be harmful if swallowed.

(Contd. on page 4)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL H

(Contd. of page 3)

- **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.
Each human donor's blood unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatite B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.
Since, nevertheless, risk of infection cannot be fully precluded the product must be handled as potentially infectious.

12 Ecological information

- **Aquatic toxicity:** At present there are no ecotoxicological assessments.
- **Persistence and degradability** Date not available
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Date not 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.
Disposal procedures have to be respected, see Section 13.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:**
Water, if necessary with cleansing agents.
Disinfectant.
- **Primary packaging:** Glass bottle

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** -
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** -
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** -
- **Packing group**
- **DOT, ADR, IMDG, IATA** -
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **SARA**
- **Section 302/304 (40CFR355.30 / 40CFR355.40):** Available information lists none.
- **Section 313 (Specific toxic chemical listings):** Not regulated.
- **TSCA (Toxic Substances Control Act):**
This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- **Proposition 65**
- **Chemicals known to cause cancer:** Available information lists none.
- **Chemicals known to cause reproductive toxicity for females:** Available information lists none.
- **Chemicals known to cause reproductive toxicity for males:** Available information lists none.
- **Chemicals known to cause developmental toxicity:** Available information lists none.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** None of the ingredient is listed.
- **IARC (International Agency for Research on Cancer)** Available information lists none.
- **NTP (National Toxicology Program)** Available information lists none.
- **TLV (Threshold Limit Value established by ACGIH)** Available information lists none.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Available information lists none.
- **OSHA-Ca (Occupational Safety & Health Administration)** Available information lists none.

(Contd. on page 5)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 04/10/2012

Reviewed on 04/10/2012

Trade name: HbA1c - CONTROL H

(Contd. of page 4)

· Product related hazard informations:

The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals and/or products potentially infectious.

· U. S. State Regulations:

· **PA-RTK** Available information lists none.

· **NJ-RTK** Available information lists none.

· **MA-RTK** Available information lists none.

· **RI-RTK** Available information lists none.

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.

· **Department issuing MSDS:** Product safety department

· **Contact:** Product safety department

· *** Data compared to the previous version altered.**

USA