

## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

### 1.1 Product identifier

**Product name** : Pointe HbA1c Control Set (CATALOG No. H7541-CTL)  
**Product code** : H7541-CTL  
**SAP Code** : 1300095177  
**Product description** : 4 x 0.5 mL (2 x 0.5 mL each level)  
**Product type** : Lyophilized

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

This product is for the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. For in vitro diagnostic use only. Rx Only

### 1.3 Details of the supplier of the safety data sheet

HORIBA Instruments Incorporated  
5449 Research Drive  
Canton, Michigan 48188  
Ph: 1-734-487-8300  
Fax: 1-734-483-1592

**e-mail address of person responsible for this SDS** : documentation.med@horiba.com

### 1.4 Emergency telephone number

#### National advisory body/Poison Centre

**Telephone number** : +44 (0)20 7771 5310

#### Supplier

**Telephone number** : 1-800-445-9853

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Product definition** : Mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.  
See Section 11 for more detailed information on health effects and symptoms.

### 2.2 Label elements

**Signal word** : No signal word.

**Hazard statements** : No known significant effects or critical hazards.

#### Precautionary statements

**Prevention** : Not applicable.

**Response** : Not applicable.

**Storage** : Not applicable.

**Disposal** : Not Applicable

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## SECTION 2: Hazards identification

**Supplemental label elements** : Not applicable.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.

### 2.3 Other hazards

**Other hazards which do not result in classification** : None known.

**Biological Hazard** : Biohazard – Use Universal Precautions when handling. Treat as potentially infectious because there is no approved test done on this product.

## SECTION 3: Composition/information on ingredients

**Substance/mixture** : Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

**Eye contact** : In case of contact, immediately flush area with plenty of water.

**Inhalation** : If inhaled move victim to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen, and call physician.

**Skin contact** : In case of contact, immediately flush area with plenty of water.

**Ingestion** : If ingested drink plenty of fluids and contact a physician.

**Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

### 4.2 Most important symptoms and effects, both acute and delayed

#### Over-exposure signs/symptoms

**Eye contact** : No specific data.

**Inhalation** : No specific data.

**Skin contact** : No specific data.

**Ingestion** : No specific data.

### 4.3 Indication of any immediate medical attention and special treatment needed

**Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

**Specific treatments** : No specific treatment.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.

**Unsuitable extinguishing media** : None known.

### 5.2 Special hazards arising from the substance or mixture

**Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.

**Hazardous combustion products** : No specific data.

### 5.3 Advice for firefighters

**Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment.

**For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

### 6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil, or air).

**Other information** : This preparation contains a small amount of sodium azide. Sodium azide is harmful to aquatic organisms and can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Prevent preparation from entering the drain and water intakes in the environment. If preparation enters the drain, flush with large amounts of water to prevent azide build up. Follow proper disposal procedures.

### 6.3 Methods and material for containment and cleaning up

**Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.  
Wash contaminated area with disinfectant.

## SECTION 6: Accidental release measures

**Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements, or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g., sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

**6.4 Reference to other sections** : See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

## SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### 7.1 Precautions for safe handling

**Protective measures** : Normal precautions for handling chemicals and potentially infectious materials must be observed (see Section 8).

**Advice on general occupational hygiene** : Eating, drinking, and smoking should be prohibited in areas where this material is handled, stored, and processed. Workers should wash hands and face before eating, drinking, and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### 7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 2 to 8°C (35,6 to 46,4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

**Recommendations** : Due to sodium azide, incompatible with acid and some metals. Forms explosion-sensitive compounds.

**Other information** : Not Available.

### 7.3 Specific end use(s)

**Recommendations** : Not available.

**Industrial sector specific solutions** : Not available.

## SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

### 8.1 Control parameters

#### Occupational exposure limits

No exposure limit value known.

**Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

**DNELs/DMELs** No DNELs/DMELs available.

**PNECs** No PNECs available

## 8.2 Exposure controls

**Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

### Individual protection measures

**Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location. Avoid contact and inhalation, do not get in eyes, on skin or on clothing. Do not pipette by mouth.

**Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. Recommended: Tightly sealed goggles according to EN 166

### Skin protection

**Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. > 8 hours (breakthrough time): Protective gloves according to EN 374 (nitrile rubber)

**Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. A lab coat is recommended.

**Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: Combination filtering device according to EN 14387 (organic vapour (Type A) and particulate filter)

**Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	: Lyophilized whole blood.
<b>Colour</b>	: Dark red in appearance.
<b>Odour</b>	: Odourless.
<b>Odour threshold</b>	: Not available.
<b>pH</b>	: Not Applicable
<b>Melting point/freezing point</b>	: Not available.
<b>Initial boiling point and boiling range</b>	: Not available.
<b>Flash point</b>	: Not applicable.
<b>Evaporation rate</b>	: Not available.
<b>Flammability</b>	: Non-flammable. In a fire, decomposition may produce toxic gases/fumes.
<b>Upper/lower flammability or explosive limits</b>	: Not available.
<b>Vapour pressure</b>	: Not available.
<b>Vapour density</b>	: Not available.
<b>Relative density</b>	: Not available.
<b>Solubility(ies)</b>	: Soluble in Water
<b>Partition coefficient: n-octanol/ water</b>	: Not available.
<b>Auto-ignition temperature</b>	: Not applicable.
<b>Decomposition temperature</b>	: Not available.
<b>Viscosity</b>	: Not available.
<b>Explosive properties</b>	: Not available.
<b>Oxidising properties</b>	: Not available.

9.2 Other information : No additional information.

## SECTION 10: Stability and reactivity

<b>10.1 Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	: The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Conditions to avoid</b>	: No specific data.
<b>10.5 Incompatible materials</b>	: No specific data.
<b>Other information</b>	: No specific data.
<b>10.6 Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological Information

### 11.1 Information on toxicological effects

#### Acute toxicity

No known significant effects or critical hazards.

#### Acute toxicity estimates

Not available.

#### Irritation/Corrosion

No known significant effects or critical hazards.

#### Sensitisation

**Conclusion/Summary** : Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

#### Specific target organ toxicity (single exposure)

Not available.

#### Specific target organ toxicity (repeated exposure)

Not available.

#### Aspiration hazard

Not available.

**Information on likely routes of exposure** : Not available.

#### Potential acute health effects

**Eye contact** : May cause irritation.

**Inhalation** : May cause irritation to mucous membranes and upper respiratory tract.

**Skin contact** : May cause irritation.

**Ingestion** : May be harmful if ingested.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No specific data.

**Inhalation** : No specific data.

**Skin contact** : No specific data.

**Ingestion** : No specific data.

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

##### Short term exposure

**Potential immediate effects** : Not available.

##### Potential delayed effects:

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**Long term exposure** : Not available

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

#### **Potential chronic health effects**

**Conclusion/Summary** : Not available.

**General** : No known significant effects or critical hazards.

**Carcinogenicity** : No known significant effects or critical hazards.

**Mutagenicity** : No known significant effects or critical hazards.

**Teratogenicity** : No known significant effects or critical hazards.

**Developmental effects** : No known significant effects or critical hazards.

**Fertility effects** : No known significant effects or critical hazards.

**Other information** : Not available.

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

**Conclusion/Summary** : Not available.

### **12.2 Persistence and degradability**

**Conclusion/Summary** : Not available.

### **12.3 Bioaccumulative potential**

Not available.

**12.4 Mobility in soil** : Not available.

**Soil/water partition coefficient ( $K_{oc}$ )** : Not available.

**Mobility**

### **12.5 Results of PBT and vPvB assessment**

**PBT** : Not applicable.

**vPvB** : Not applicable.

**12.6 Other adverse effects** : No known significant effects or critical hazards.

## **SECTION 13: Disposal considerations**

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

### **13.1 Waste treatment methods**

#### **Product**

**Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

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**Hazardous waste** : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

**Packaging**

**Methods of disposal** : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

**Special precautions** : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

**SECTION 14: Transport information**

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

**14.6 Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**SECTION 15: Regulatory information**

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

**EU Regulation (EC) No. 1907/2006 (REACH)**

**Annex XIV - List of substances subject to authorisation**

**Annex XIV**

None of the components are listed.

**Substances of very high concern**

None of the components are listed.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.

**Other EU regulations**

**Ozone depleting substances (1005/2009/EU)**

Not listed.

**Prior Informed Consent (PIC) (649/2012/EU)**

Not listed.

### Seveso Directive

This product is not controlled under the Seveso Directive.

### National regulations

**Biocidal products regulation** : Not applicable.

### International regulations

### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

### Montreal Protocol (Annexes A, B, C, E)

Not listed.

### Stockholm Convention on Persistent Organic Pollutants

Not listed.

### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

### Inventory list

<b>Australia</b>	: All components are listed or exempted.
<b>Canada</b>	: All components are listed or exempted.
<b>China</b>	: All components are listed or exempted.
<b>Europe</b>	: All components are listed or exempted.
<b>Japan</b>	: <b>Japan inventory (ENCS)</b> : All components are listed or exempted. <b>Japan inventory (ISHL)</b> : Not determined.
<b>Malaysia</b>	: Not determined.
<b>New Zealand</b>	: All components are listed or exempted.
<b>Philippines</b>	: All components are listed or exempted.
<b>Republic of Korea</b>	: All components are listed or exempted.
<b>Taiwan</b>	: All components are listed or exempted.
<b>Thailand</b>	: Not determined.
<b>Turkey</b>	: Not determined.
<b>United States</b>	: All components are listed or exempted.
<b>Viet Nam</b>	: All components are listed or exempted.

**15.2 Chemical safety assessment** : Not applicable.

## **SECTION 16: Other information**

**Revision comments** : Modification of section 8: new data available

📌 Indicates information that has changed from previously issued version.

## SECTION 16: Other information

### Abbreviations and acronyms

: ATE = Acute Toxicity Estimate  
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]  
DMEL = Derived Minimal Effect Level  
DNEL = Derived No Effect Level  
EUH statement = CLP-specific Hazard statement  
PBT = Persistent, Bioaccumulative and Toxic  
PNEC = Predicted No Effect Concentration  
RRN = REACH Registration Number  
vPvB = Very Persistent and Very Bioaccumulative

### Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

### Full text of abbreviated H statements

Not applicable.

### Full text of classifications [CLP/GHS]

Not applicable.

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### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.