
 CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	HbA1C-Reagent R1		SDS	 IVD	Rev.A - 09-06- 22
		REF	R3330000001			
			A-R0000000029			
	A-R0000000030					

Safety Data Sheet (According to 1272/2008/EC)

Trade name: **HbA1c**
Article number: **R3330000001, A-R0000000029, A-R0000000030**
Product Description: **Hemoglobin A1c - Reagent R1**

1 Identification of the substance / preparation and the company

1.1 Product identifiers

Product REF: Refer to the Header
Product Description: Refer to the Header

1.2 Relevant identified uses of the substance or mixture and uses advices against

In vitro diagnostics.

1.3 Details of the supplier of the safety data sheet

Identification company: I.S.E. S.r.l.
Via delle Driadi, 45
00133 Roma - Italia
Tel. +39 0774+ 579365; FAX +39 0774 579305
E-mail: info@logotech-ise.com www.logotech-ise.com

Additional information from: I.S.E. S.r.l. - Regulatory Affairs E-mail: info@logotech-ise.com

1.4 Emergency telephone number

Emergency information: As above or call
Policlinico A. Gemelli - Largo Agostino Gemelli, 8 - Roma - Italy - Tel. + 39 063054343

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008

Void

For the full text of the H-Statements mentioned in the Section, see Section 16




Hazard designation: Void

2.2 Label elements

Labelling according to EC regulation 1272/2008

Label: Void
Signal word: Void
Hazard statements: Void
Precautionary statements: Void
Information pertaining to
particular dangers for man and
environment: Void



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2.3 Other hazards

Hazardous properties cannot be excluded.

Sodium azide can form explosive azides when containing heavy metals such as copper or lead.

3 Composition / information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Chemical characterization: Mixture

Description: Mixture of the substances listed below with harmless products

Hazardous components:	Sodium azide	CAS: 26628-22-8	<u>Acc.1272/2008:</u>
	< 0.1%	EC: 247-852-1	Acute Tox Oral CAT 4; H302
		Index Number:	Acute Aquatic Tox CAT 3; H412
		011-004-00-7	

Additional information: For the wording of the listed phrases refer to Section 16
This reagent contains Sodium Azide as a preservative

4 First aid measures

4.1 Description of first aid measures

General information: Remove contaminated clothing



After inhalation: Supply fresh air, consult doctor in case breathing problems develop. Unconscious: maintain adequate airway and respiration.

After skin contact: Wash with soap and water. If symptoms persists, consult doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persists, consult doctor. Do not apply neutralizing agents.

After swallowing: Rinse out mouth and then drink plenty of water. In case of persistent symptoms, consult doctor.



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4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing agents: Carbon dioxide (CO₂), extinguishing powder or water spray/fog. Fight larger fires with water spray/fog or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents: None.

5.2 Special hazards arising from the substance or mixture

Special hazard caused by the material, its products of combustion or flue gases: Nitrogen oxides (Nox), Oxides of phosphorus (PxOy) Carbon monoxide (CO) and Carbon dioxide (CO₂)

5.3 Advice for firefighters

Protective equipment: Put on breathing apparatus. Gas-tight suit.

Additional information: Collect contaminated firefighting water separately. It must not enter drains.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Person-related safety precautions: Wear protective clothing. Do not breathe vapors. Avoid skin and eye contact. See Section 8.




6.2 Environmental precautions

Measures for environmental protection: Do not allow to enter drainage system, surface or ground water. Discharge according local regulations.

6.3 Methods and material for containment and cleaning up

Measures for cleaning/collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose of contaminated material as waste according to item 13.
Clean contaminated surfaces with an excess of water.
Wash clothing and equipment after handling.



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6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Information for safe handling: Observe normal to strict hygiene standards.
Handle and open the container with care.
Ensure good ventilation / exhaustion at the workplace.
Do not inhale aerosols.
Avoid prolonged or repeated skin contact.
Avoid contact with eyes.
Make sure that all applicable workplace limits are observed.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and containers: Observe all local and national regulations for storage of water polluting products.

Information about storage in one common storage facility: Not required

Further information about storage conditions: Keep container tightly sealed.
Protect from heat and direct sunlight.
Store in a cool place.
Recommend storage temperature: 2 - 8 °C.

7.3 Specific end use(s)

Void.




8 Exposure controls / personal protection

8.1 Control parameters

Additional information about design of technical systems: No further data; see item 7.

Components with critical values that require monitoring at the workplace:	Sodium azide	WEL (Great Britain)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³
		TLV (European Union)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin



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Additional information: The list that were valid during the compilation were used as basis.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures: Keep away from foodstuffs, beverages and food.
Do not inhale gases / fumes / aerosols.
Avoid close or long term contact with the skin.
Avoid contact with the eyes.
Wash hands during breaks and at the end of the work.

Breathing equipment: If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

Protection of hands: Protective gloves. The glove material has to be impermeable and resistant to the product / the substance / the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
Check the permeability prior to each new use of the glove.
To avoid skin problems reduce the wearing of gloves to the required minimum. Due to missing tests no recommendation to the glove material can be given for the product / the preparation / the chemical mixture.

Material of gloves: The selection of the suitable gloves does not only depend on the material but also on further marks of quality varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of the glove: The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General information

Appearance: Liquid




Colour: Milky White

Odour: Odourless

Odour threshold: No data available

pH value: No data available



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Change in condition:

Melting point / Melting range:	No data available
Boiling point / Boiling range:	No data available
Evaporation rate:	No data available
Flash point / Flash point range:	Not applicable
Self-inflammability:	Product is not self-igniting.
Danger of explosion:	Product is not explosive.
Density:	No data available
Solubility in / Miscibility with water:	Soluble

9.2 Other information

No data available

10 Stability and reactivity

10.1 Reactivity

Stable reactivity until expiry date if stored in recommended conditions.

10.2 Chemical stability

Stable until expiry date under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.




10.4 Conditions to avoid

Thermal decomposition / conditions to be avoided:	Sunlight Heat
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10.5 Incompatible products

Materials to be avoided:	Strong oxidizing agents Strong acids Heavy metals
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10.6 Hazardous decomposition products

Dangerous reactions may form very sensitive explosive metallic compounds.

Dangerous products of decomposition: Nitrogen oxides (Nox), Oxides of phosphorus (PxOy)
Carbon monoxide (CO) and Carbon dioxide (CO2)

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD/LC50 values that are relevant for classification:	Sodium azide	Oral	LD50	27 mg/kg (rat)
		Dermal	LD50	20 mg/kg (rabbit)

Primary irritant effect

on the skin: No irritant effect.

on the eye: No irritant effect.

Sensitization: No sensitizing effect known.

Additional toxicological information: The product is not object to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version. 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

12.1 Toxicity

Ecotoxicological effects

Aquatic toxicity:	Sodium Azide	LC50/96 h	0.7 mg/L (bluegill (Iepomis macrochirus))
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12.2 Persistence and degradability

No data available.



12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.



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12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

Water hazard class 1 (self-assessment): Slightly hazardous for water.

13 Disposal considerations

13.1 Waste treatment methods

Product

Recommendation: Disposal must be made according to official regulations.

European waste catalogue: Waste disposal key numbers from EWC have to be assigned depending on origin and processing.

Contaminated packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleaning agent: Water, if necessary with cleaning agent.

14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA: Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA: Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA: Not applicable




14.4 Packaging group

ADR/RID, IMDG, IATA: Not applicable

14.5 Environmental hazards

Marine pollutant: No



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14.6 Special precautions for user

No dangerous goods in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available.

15 Regulatory information

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

Designation according to EC guidelines: The product needs to be classified and labelled in accordance with EC Directives / relevant national laws.

National regulations

Degree to be applied in case of technical fault: -

Water hazard class

Water hazard class 1 (self-assessment): Slightly hazardous for water

15.2 Chemical Safety Assessment

Void

16 Other information

Relevant R-phrases: The(se) R-phrases are of the ingredient(s) and of do(es) NOT represent the classification of the preparation.

28 Very toxic if swallowed

32 Contact with acids liberates very toxic gas

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Hazard statements: H302 Harmful if swallowed




H412 Harmful to aquatic life with long lasting effects

Precautionary statements: P301+312 If swallowed, call a poison center/doctor/... if you feel unwell

P330 Rinse mouth

P264 Wash hands thoroughly after handling



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P270 Do not eat, drink or smoke when using this product

P273 Avoid release to the environment

P501 Dispose of content/container to ... in accordance with local/regional/national/international regulations

In vitro diagnostics use only.

Sodium azide is been used as preservative. Products containing Sodium azide must be handled with due caution: do not ingest or allow to contact skin or mucous membranes!

Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

Each human donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

Department issuing SDS: I.S.E. S.r.l., Regulatory Affair Office

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3



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