

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1. Product Identifier**

SDS # BIO-004-EU
Product Code 7011/7011R
7010/7010R
7009/7009R
Product Name Diabetes Autoimmune ELISA Kits
Synonyms IAA ELISA Kits
ICA ELISA Kits
GAD ELISA Kits
Contains Sodium hydroxide

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Recommended Use For research or in vitro diagnostic use only
Uses Advised Against Not for use on or in humans

1.3. Details of the Supplier of the Safety Data Sheet

Supplier
Biomerica
17571 Von Karman Avenue
Irvine, CA 92614, USA
1-800-854-3002

For further information, please contact

Email Address brma@biomerica.com

1.4. Emergency telephone number

Emergency Telephone (24 hr) INFOTRAC 1-352-323-3500 (International)
1-800-535-5053 (North America)

Section 2: HAZARDS IDENTIFICATION**2.1. Classification of the Substance or Mixture**
Regulation (EC) No 1272/2008

Skin corrosion/irritation	Category 1 Sub-category B - (H314)
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2.2. Label Elements

Product Identifier
Contains Sodium hydroxide



Signal Word

Danger

Hazard statements

H314 - Causes severe skin burns and eye damage

Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P310 - Immediately call a POISON CENTER or doctor/physician

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P405 - Store locked up

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other Hazards

Calibrators are formulated with a buffer base, animal or human serum. The kit components that are made with human serum are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen, and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988. All bovine serum products used are derived from animals of US origin, processed in USDA licensed facilities. Calibrators are formulated with Sodium Azide as a preservative. Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. It may also react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. MIXTURES

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Sodium hydroxide	Present	1310-73-2	4	Skin Corr. 1A (H314)	Not determined
Sodium azide	Present	26628-22-8	<0.1	(EUH032) Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not determined

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Section 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

Eye Contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Call a doctor immediately.

Skin Contact

Wash with soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.

Inhalation

Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, give oxygen. Get medical attention if necessary.

Ingestion	Flush mouth with copious amounts of water, provided that the person is conscious, and seek medical attention. Do NOT induce vomiting.
Self-Protection of the First Aider	No specific precautions necessary.

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms	May cause irritation to the mucous membranes and upper respiratory tract. Skin contact can lead to drying, defatting, itching, stinging and irritation. Causes serious eye damage.
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4.3. Indication of any Immediate Medical Attention and Special Treatment Needed

Notes to Physician	Treat symptomatically.
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Section 5: FIREFIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media

Chemical or water fire extinguisher.

Unsuitable Extinguishing Media

None known.

5.2. Special Hazards Arising from the Substance or Mixture

Calibrators in kits are formulated with Sodium Azide as a preservative. Sodium Azide may react with copper and lead plumbing to form explosive metal azides that are sensitive to mechanical shock, concussion, friction, and sparks. May react with acids to form explosive hydrazoic acid.

5.3. Advice for Firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment as required.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions

Wear protective clothing as described in Section 8 of this safety data sheet. Take care not to contaminate body.

For Emergency Responders

Use personal protection recommended in Section 8.

6.2. Environmental Precautions

Contain the spill to the smallest area possible. See Section 12 for additional Ecological Information.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Containment

Prevent further leakage or spillage if safe to do so.

Methods for Clean-Up

Neutralize a Stop Solution spill with dilute acid, then absorb the material with disposable towels. Soak a Calibrator spill area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

6.4. Reference to Other Sections

See Section 13: DISPOSAL CONSIDERATIONS.

Section 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Advice on Safe Handling

Use personal protection recommended in Section 8. Take care not to splash, spill, or splatter standards, stop solution, or controls. Do not breathe dust/fume/gas/mist/vapours/spray. Wash face, hands and any exposed skin thoroughly after handling.

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions

Store kit reagents in 2-8°C in refrigerators designated and labeled to contain human blood products. Store locked up.

7.3. Specific End Use(s)

Specific Use(s)

For research or in vitro diagnostic use only.

Risk Management Methods (RMM)

The information required is contained in this Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Exposure Limits

Chemical Name	European Union	United Kingdom	France	Spain	Germany
Sodium hydroxide 1310-73-2	-	STEL: 2 mg/m ³	TWA: 2 mg/m ³	STEL: 2 mg/m ³	-
Sodium azide 26628-22-8	S* TWA 0.1 mg/m ³ STEL 0.3 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	S* STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.2 mg/m ³
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Sodium hydroxide 1310-73-2	-	Ceiling: 2 mg/m ³	-	STEL: 2 mg/m ³ Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	STEL: 0.3 mg/m ³ Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm TWA: 0.1 mg/m ³	Skin STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ Skin
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Sodium hydroxide 1310-73-2	STEL 4 mg/m ³ TWA: 2 mg/m ³	STEL: 2 mg/m ³ TWA: 2 mg/m ³	STEL: 1 mg/m ³ TWA: 0.5 mg/m ³	Ceiling: 2 mg/m ³	STEL: 2 mg/m ³
Sodium azide 26628-22-8	Skin STEL 0.3 mg/m ³ TWA: 0.1 mg/m ³	STEL: 0.4 mg/m ³ TWA: 0.2 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin

8.2. Exposure Controls

Engineering Controls

Apply technical measures to comply with the occupational exposure limits.

Personal Protective Equipment

Eye/Face Protection

Wear approved safety goggles where a splash hazard exists.

Hand Protection

Wear non-permeable rubber, neoprene, latex, or nitrile disposable gloves. Change gloves when they become contaminated.

Skin and Body Protection

Wear laboratory coat.

Respiratory Protection

In case of fire, wear self-contained breathing apparatus.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical state	Liquid	Odour	No detectable odor
Appearance	Clear liquid	Odour Threshold	Not determined
Colour	Clear		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	7.0-7.4	Stop Solution pH >12
Melting Point/Freezing Point	0 °C / 32 °F	
Boiling Point/Boiling Range	100 °C / 212 °F	
Flash Point	Not applicable	
Evaporation Rate	Not determined	
Flammability (Solid, Gas)	Not flammable	
Flammability Limits in Air		
Upper Flammability Limits	Not applicable	
Lower Flammability Limit	Not applicable	
Vapour Pressure	Not applicable	
Vapour Density	Not determined	
Relative Density	1-3	(Water = 1)
Water Solubility	Completely soluble	
Solubility(ies)	Not determined	
Partition Coefficient	Not determined	
Auto-ignition Temperature	Will not occur	
Decomposition Temperature	Not determined	
Kinematic Viscosity	Not determined	
Dynamic Viscosity	Not determined	
Explosive Properties	Not determined	
Oxidising Properties	Not determined	

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Not reactive under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of Hazardous Reactions

Possibility of Hazardous Reactions

None under normal processing.

10.4. Conditions to Avoid

Contact with incompatible materials.

10.5. Incompatible Materials

Lead. Mild steel. Copper

10.6. Hazardous Decomposition Products

None known.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity

Product Information

Potential biohazard.

Inhalation	Do not inhale.
Eye Contact	Causes serious eye damage.
Skin Contact	Avoid contact with skin.
Ingestion	Do not ingest.

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	27,000.00 mg/kg
ATEmix (dermal)	33,750.00 mg/kg

Unknown Acute Toxicity

- 5.5 % of the mixture consists of ingredient(s) of unknown toxicity.
- 5.5 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
- 1.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 5.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
- 5.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).
- 5.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide		= 1350 mg/kg (Rabbit)	
Sodium azide	= 27 mg/kg (Rat)	= 50 mg/kg (Rat) = 20 mg/kg (Rabbit)	

Skin corrosion/irritation	Not classified.
Serious eye damage/eye irritation	Not classified.
Sensitisation	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Aspiration hazard	Not classified.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Sodium hydroxide		45.4: 96 h Oncorhynchus mykiss mg/L LC50 static	

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Sodium azide		0.7: 96 h Lepomis macrochirus mg/L LC50 5.46: 96 h Pimephales promelas mg/L LC50 flow-through 0.8: 96 h Oncorhynchus mykiss mg/L LC50	

12.2. Persistence and Degradability

Not determined.

12.3. Bioaccumulative Potential

Not determined.

12.4. Mobility in Soil

Mobility in Soil

Not determined.

Mobility

Not determined.

12.5. Results of PBT and vPvB Assessment

Not determined.

12.6. Other Adverse Effects

Not determined.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste from Residues / Unused Products

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging

Improper disposal or reuse of this container may be dangerous and illegal.

Section 14: TRANSPORT INFORMATION

IMDG

- 14.1 UN/ID No UN1814
- 14.2 Proper Shipping Name Sodium hydroxide, solution
- 14.3 Hazard Class 8
- 14.4 Packing Group III

RID

- 14.1 UN/ID No UN1814
- 14.2 Proper Shipping Name Sodium hydroxide, solution
- 14.3 Hazard Class 8
- 14.4 Packing Group III

ADR

- 14.1 UN/ID No UN1814
- 14.2 Proper Shipping Name Sodium Hydroxide Solution
- 14.3 Hazard Class 8
- 14.4 Packing Group III

IATA

14.1 UN/ID No UN1814
 14.2 Proper Shipping Name Sodium hydroxide, solution
 14.3 Hazard Class 8
 14.4 Packing Group III

Section 15: REGULATORY INFORMATION

15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

Component	TSCA	DSL/NDSL	EINECS/ELINCS	PICCS	ENCS	IECSC	AICS	KECL
Sodium hydroxide 1310-73-2 (4)	X	X	X	X	Present	X	X	Present
Sodium azide 26628-22-8 (<0.1)	X	X	X	X	Present	X	X	Present

Legend

- TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
- EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
- PICCS - Philippines Inventory of Chemicals and Chemical Substances
- ENCS - Japan Existing and New Chemical Substances
- IECSC - China Inventory of Existing Chemical Substances
- AICS - Australian Inventory of Chemical Substances
- KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Section 16: OTHER INFORMATION

Full text of H-Statements referred to under section 3

- H314 - Causes severe skin burns and eye damage
- H300 - Fatal if swallowed
- H400 - Very toxic to aquatic life
- H410 - Very toxic to aquatic life with long lasting effects
- EUH032 - Contact with acids liberates very toxic gas

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)
 Ceiling Maximum limit value * Skin designation

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Classification Procedure

Calculation method

Issue Date: 01-Dec-1997

Revision Date: 20-Nov-2017

Revision Note: Regulatory update.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Regulation (EU) No. 453/2010

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet