

Trade name: Insulin rat ELISA
 Product number: DEV8811

Date of Issue: 29-11-2012

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1. Identification of the substance/preparation and of the company

Product name: INSULIN RAT ELISA KIT
 Product code: DEV8811
 Product formal name: Research reagent
 Application of the substance/preparation: For In-vitro research test KIT
 Manufacturer/Supplier: Demeditec Diagnostics GmbH
 Lise-Meitner-Str.2
 24145 Kiel
 Germany
 Phone number: +49(0)431-71922-0
 Fax number: +49(0)431-71922-55

Further information available from: www.demeditec.com
 Email address of the competent person: info@demeditec.de
 Information in case of emergency: +49(0)431-71922-0

2. Hazards identification:

2.1 Classification of the substance or mixture of the KIT

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

Acute toxicity, Oral, Dermal(Category 2, Category 1)

Acute aquatic toxicity (Category 1)

Chronic aquatic toxicity (Category 1)

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]



* Pictograms:

Signal word: Danger

Hazard statements:

See at the list of dangerous components (page 3)

Precautionary statements:

See at the list of dangerous components (page 3)

** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labeling necessary as the total volume of the components of the KIT is under 125 ml.*

Information concerning particular hazards for human and environment:

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Harmful if swallowed. Irritating to eyes and skin. Causes burns.

2.3 Other hazards

Additional information:

1. **Sodium azide** is a toxic substance. Avoid contact with components, which contain sodium azide and do not ingest.
2. **Thimerosal** is a toxic substance. Avoid contact with skin, eyes and clothing.
3. **Biologically derived materials:** All components (except STOP reagent and wash buffer concentrate) may contain human or animal biologically derived materials.




Trade name: Insulin rat ELISA
Product number: DEV8811

3. Composition / Information on ingredients:

Component No.	Component Name	Description
1	CONJUGATE	1 bottle (13 mL) , HRPO-conjugated antibodies in buffer
2	ANTISERUM	1 bottle (11 mL), Biotin-conjugated antibodies in buffer
3	STANDARDS	7 vials (S0 - 2 mL; S1-S6 - 0.5 mL), ready to use, containing protein
4	COATED MICRO-TITRE PLATE	Protein coated polystyrene microplate
5	SUBSTRATE	1 bottle (25 mL) , containing enzyme substrate in buffer
6	WASHING BUFFER CONCENTRATE	1 bottle (50 mL), containing detergent in buffer
7	STOP REAGENT	1 bottle (6 mL), containing diluted H ₂ SO ₄

Component No.	Hazard description
1	Contains animal origin, biologically derived material and thimerosal as preservatives (< 0.01%)
2	Contains animal origin, biologically derived material and thimerosal as preservatives (< 0.01%)
3	Contains animal origin, biologically derived material material and sodium azide as preservatives (< 0.1%)
4	Contains animal origin, biologically derived material
5	Contains animal origin, biologically derived material
6	Contains detergent in buffer and thimerosal as preservatives (< 0.1%)
7	Sulphuric acid, 1 M

List of the dangerous components: Sodium azide, Thimerosal, Sulphuric acid

International chemical identification			CAS #	EC No
Sodium azide (Component No. 3)			26628-22-8	247-852-1
Classification		Labelling		
<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>	
Acute tox. 2	H300	EUH 032	GHS05 GHS06 GHS09	
Aquatic Acute 1	H400			
Aquatic Chronic 1	H410			
Signal words		Pictogram(s)		
Danger				
		Skull and crossbones	Environment	Corrosive to metals




Hazardous statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Trade name: Insulin rat ELISA
 Product number: DEV8811

Precautionary statements:

P273 Avoid release to the environment.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P301 + P310 + P330 If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
 P302 + P352 + P310 If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
 P391 Collect spillage.
 P501 Dispose of contents/container as waste: in an approved waste.

International chemical identification			CAS #	EC no
Thimerosal (Component No. 1,2,6)			54-64-8	200-210-4
Classification		Labelling		
<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>	
Acute tox. 2	H300	-	GHS06 GHS08 GHS09	
Acute tox. 1	H300 H310			
Acute tox. 2	H330			
Aquatic Acute 1	H400			
Aquatic Chronic 1	H410			
Eye irritation 2B	H320			
Signal words		Pictogram(s)		
Danger				
		Skull and crossbones	Environment	Health hazard


Hazardous statements:

H300 Fatal if swallowed
 H310 Fatal in contact with skin
 H320 Causes eye irritation
 H330 Fatal if inhaled
 H400 Very toxic to aquatic life
 H410 Very toxic to aquatic life

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 P264 Wash hands thoroughly after handling.
 P273 Avoid release to the environment.
 P280 Wear protective gloves / protective clothing.
 P284 Wear respiratory protection.
 P302 + P350 IF ON SKIN: Gently wash with plenty of soap and water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses.
 P310 Immediately call a POISON CENTER or doctor/physician.

Trade name: Insulin rat ELISA
Product number: DEV8811

International chemical identification		CAS #	EC no
Sulphuric acid (Component 7)		7664-93-9	231-639-5
Classification		Labelling	
<i>Hazard class and Category Code(s)</i>	<i>Hazard statement Code(s)</i>	<i>Supplementary hazard statement Code(s)</i>	<i>Pictogram(s), signal word Code(s)</i>
Corrosive to metals 1	H 290	-	GHS05
Skin corrosion 1A, 1B, 1C	H314		
Serious eye damage	H314		
Signal words		Pictogram(s)	
Danger		 Corrosion	

Hazardous statements:

H290 May be corrosive to metals
H314 Causes severe skin burns and eye damage

Precautionary statements:

P280 Wear protective gloves / protective clothing.
P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off Immediately all PP30 contaminated clothing. Rinse SKIN with water/shower.
P304 + 340 + 310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
P305 + P 351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses.

4. First Aid:

After inhalation: Remove victim to fresh air. If breath labored, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: Flush with copious amount of fresh water for at least 15 minutes.
Stop reagent: Assure adequate flushing by separating the eyelids with fingers. Call a physician.

After skin contact: Wash well with mild soap and copious amount of fresh water.
Stop reagent: remove contaminated clothing and shoes. Call a physician.

After swallowing: Flush mouth with copious water (do not swallow rinse water).
Stop reagent: Do not induce vomiting. Call a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently. If possible, save sample of material that caused reaction for use in determination of appropriate treatment.

5. Fire extinguishing measures:

Suitable extinguishing agents: Use extinguishing media (dry sand, cement) appropriate to surrounding fire. Dangerous gases, which are damaging to health, do not form in dangerous quantities.

Extinguishing agents not to be used: None known.

Protective equipment: No special equipment or procedures are required.

6. Accidental release measures:

Personal precaution: Ensure adequate ventilation. Use personal protective equipment.

Environmental precaution: Prevent further leakage or spillage of safe to do so.

Trade name: Insulin rat ELISA
Product number: DEV8811

Methods for cleaning up, after spillage:

Biological vials: Absorb spills of reagents and patient samples with absorbent paper. Clean spill area with a freshly prepared sodium hypochlorite (bleach) solution and absorb it.

Stop reagent: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Use neutralizing agent (sodium hydroxide solution or calcium carbonate or sodium carbonate powder).

7. Handling and storage:

Handling: Wear suitable personal protective equipment. Do not pipette patient samples or reagents by mouth. Avoid splashing. Use all reagents in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

Stop reagent: Do not get in eyes, on skin, on clothing. Avoid prolonged or repeated exposure.

Storage: Store kit reagents in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

Stop reagent: Keep tightly closed.

8. Exposure controls/personal protection:
Personal protective equipment:

Body and skin protection: Wear laboratory coat.

Respiratory protection: Under normal and intended conditions of use not required. In case of fire, wear self-contained breathing apparatus.

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

Skin protection: Wash hands after working with substance.

Eye protection: Wear safety glasses or goggles when splash hazard exists.

Hygienic measures: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. Keep away from food and drink.

Stop reagent: Wash contaminated clothing before reuse. Discard contaminated shoes. Wash thoroughly after handling.

Additional information: Avoid contact with skin and/or mouth. Avoid absorption through non-protected wound. Avoid splashing or aerosol formation. Use all reagents in accordance with the relevant package insert. Swallowing of **stop reagent** (component No. 7) will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

9. Physical and chemical properties:

Component No.	1	2	3	4	5	6	7
Physical state	liquid	liquid	liquid	solid	liquid	liquid	liquid
Colour	blue	red	yellow	clear	clear	clear	clear
Odour	odourless	odourless	odourless	odourless	odourless	odourless	odourless
pH	7.5 – 8.5	7.2 – 7.6	7.2 – 7.6	N/A	3.0 – 4.0	9.0 – 10.0	< 1
Solubility in water	complete	complete	complete	N/A	complete	complete	complete
Melting point	0 °C	0 °C	0 °C	ca.240 °C	0 °C	0 °C	0 °C
Boiling point	100 °C	100 °C	100 °C	N/A	100 °C	100 °C	100 °C
Flammability	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Auto flammability	Will not occur	Will not occur	Will not occur	Will not occur	Will not occur	Will not occur	Will not occur
Vapour pressure	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Relative Density	1-2	1-2	1-2	N/A	1-2	1-2	1-2

Trade name: Insulin rat ELISA
Product number: DEV8811

10. Stability and reactivity:
Reactivity:

No hazardous reactions when used appropriately.

Stability:

The reagents in the kit are stable under the storage conditions described in the package insert.

Materials to avoid:

Avoid contact with acids, bases, oxidizing agents, reducing agents, explosive, heavy metals and metallic salts (explosive metal azide complex, when azide built up occur).

Hazardous decomposition products: None known.

Stop reagent: Sulphur oxides.

Hazardous polymerization:

Will not occur.

Conditions to avoid:

None known.

11. Toxicological information:
Signs and symptoms of exposure:

The chemical, physical, and toxicological properties have not been thoroughly investigated.

Stop reagent: Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting. Inhalation may result in spasm, inflammation and oedema of the larynx and bronchi, chemical pneumonitis, and pulmonary oedema.

Route of exposure:
Skin contact:

May cause skin irritation.

Skin absorption:

Danger of skin absorption, may be harmful if absorbed through the skin.

Eye contact:

May cause eye irritation.

Inhalation:

May be harmful if inhaled. May cause irritations of mucous membranes and upper respiratory tract.

Ingestion:

Harmful if swallowed. May cause irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

Additional information:

This product contains a chemical known to cause cancer and reproductive harm.

12. Ecological information:
Ecotoxic effects:

Sodium azide and thimerosal are toxic for aquatic organisms.

13. Disposal considerations:
Product / packaging:

Contact appropriate local authorities, approved waste disposal companies who will advise you on how to dispose of special waste.

If drain disposed, dilute and flush with copious amount of running water to prevent azide build-up.

14. Transport information:
Land transport ADR/RID:

Not subject to transport regulations.

Sea transport IMDG:

Not subject to transport regulations.

Air transport ICAO/IATA:

Not subject to transport regulations.

15. Regulatory information:
Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

Hazard-determining components of labelling: *NaN₃, Sulphuric acid and Thimerosal
** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labeling necessary as the total volume of the components of the KIT is under 125 ml.*

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16. Other information:

- All animal products and derivatives are collected in healthy animals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- For in vitro research use only.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- Use protective clothing and disposable gloves.