

#### SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830

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Version:	11
Language:	en-GB,IE
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# SECTION 1: Identification of the substance/mixture and of the company/undertaking

### **1.1 Product identifier**

Immunoglobulin M FS Reagent R1 As part of the kits: 1 7222 XX XX XXX (The positions X code different packages.)

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

General use:

Trade name

Reagent for in-vitro diagnostics in human samples For professional use only

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

Company name:	DiaSys Diagnostic Systems GmbH
Street/POB-No.:	Alte Strasse 9
Postal Code, city:	65558 Holzheim
WWW:	http://www.diasys.de
E-mail:	mail@diasys.de
Telephone:	+49 (0) 6432-9146-0
Telefax:	+49 (0) 6432-9146-32
Department responsible for information:	

Department responsible fo

Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: mail@diasys.de

### 1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

# **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

### Classification according to EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

### 2.2 Label elements

### Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

### 2.3 Other hazards

No risks worthy of mention.

Results of PBT and vPvB assessment: No data available



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# **SECTION 3: Composition / information on ingredients**

### 3.1 Substances: not applicable

### 3.2 Mixtures

Chemical characterisation: Aqueous solution

Additional information:Preparation does not contain dangerous substances above limits that need to be<br/>mentioned in this section according to applicable legislation.Contains Polyethylene glycol. The maximum workplace exposure limits are, where<br/>necessary, listed in section 8.

Contains Sodium azide (0.95 g/L) as preservative.

# **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

- Following skin contact: Change contaminated clothing. Remove residues with water. In case of skin reactions, consult a physician.
- After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an opthalmologist.
- After swallowing: Rinse mouth thoroughly with water. Induce vomiting. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

Never give anything by mouth to an unconscious person.

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

No data available

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

Treat symptomatically.

# **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

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

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

### 5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information: Hazchem-Code: -

Do not allow fire water to penetrate into surface or ground water.



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# **SECTION 6: Accidental release measures**

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

Do not breathe vapours. Avoid contact with skin and eyes. Wear appropriate protective equipment.

Provide adequate ventilation.

### 6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

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

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

### 6.4 Reference to other sections

Refer additionally to section 8 and 13.

# **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Advices on safe handling: Do not breathe vapours. Avoid contact with skin and eyes. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Provide adequate ventilation, and local exhaust as needed.

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

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light. Keep sterile.

### 7.3 Specific end use(s)

No information available.

# **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

### Personal protection equipment

### Occupational exposure controls

Respiratory protection:	If vapours form, use respiratory protection. Use filter type A (= against vapours of organic substances) according to EN 14387.
Hand protection:	Protective gloves according to EN 374. Glove material: Nitrile rubber. Breakthrough time: >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.



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Eye protection:

Tightly sealed goggles according to EN 166. Body protection: Lab coat

General protection and hygiene measures:

When using do not eat or drink. Do not breathe vapours. Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work.

# **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Colour: colourless, clear
Odour:	like polyethylene oxide adduct
Odour threshold:	No data available
pH:	at 25 °C: 7.5
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 °C: 1.018 g/mL
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available

### 9.2 Other information

Additional information:

No data available

# **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

refer to 10.3

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known.



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### 10.4 Conditions to avoid

Protect against heat /sun rays.

### **10.5 Incompatible materials**

Thermal decomposition:

Strong acids, alkalis

### 10.6 Hazardous decomposition products

No decomposition when used properly. In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide. No data available

# **SECTION 11: Toxicological information**

### 11.1 Information on toxicological effects

Acute toxicity (oral): Lack of data.
Acute toxicity (dermal): Lack of data.
Acute toxicity (inhalative): Lack of data.
Skin corrosion/irritation: Lack of data.
Serious eye damage/irritation: Lack of data. May cause irritations.
Sensitisation to the respiratory tract: Lack of data.
Skin sensitisation: Lack of data.
Germ cell mutagenicity/Genotoxicity: Lack of data.
Carcinogenicity: Lack of data.
Reproductive toxicity: Lack of data.
Effects on or via lactation: Lack of data.
Specific target organ toxicity (single exposure): Lack of data.
Specific target organ toxicity (repeated exposure): Lack of data.
Aspiration hazard: Lack of data.
Contains Sodium azide (0.95 g/L): After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

# **SECTION 12: Ecological information**

### 12.1 Toxicity

Further details: No data available

### 12.2 Persistence and degradability

Further details:

# 12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

No data available



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### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

No data available

### 12.6 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

# **SECTION 13: Disposal considerations**

### 13.1 Waste treatment methods

### Product

 Waste key number:
 16 05 06\* =
 Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.

 \* = Evidence for disposal must be provided.

 Recommendation:
 Special waste. Dispose of waste according to applicable legislation.

### Package

Waste key number:	15 01 02 = Plastic packaging
Recommendation:	Dispose of waste according to applicable legislation.
	Non-contaminated packages may be recycled.

# **SECTION 14: Transport information**

### 14.1 UN number

ADR/RID, IMDG, IATA-DGR:

not applicable

### 14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR:

Not restricted

### 14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:

not applicable

### 14.4 Packing group

ADR/RID, IMDG, IATA-DGR:

not applicable

### 14.5 Environmental hazards

Marine pollutant:

no

### 14.6 Special precautions for user

No dangerous good in sense of these transport regulations.



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### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

# **SECTION 15: Regulatory information**

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

### National regulations - Great Britain

Hazchem-Code:

No data available

### **15.2 Chemical Safety Assessment**

For this mixture a chemical safety assessment is not required.

# **SECTION 16: Other information**

### **Further information**

Abbreviations and acronyms

Abbreviations and acrony	/ms:
	ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
	ADR: European Agreement concerning the International Carriage of Dangerous Goods by
	Road
	AS/NZS: Australian Standards/New Zealand Standards
	CAS: Chemical Abstracts Service
	CFR: Code of Federal Regulations
	CLP: Classification, Labelling and Packaging
	CNS: Central Nervous System
	DMEL: Derived minimal effect level
	DNEL: Derived no-effect level
	EC: European Community
	EN: European Standard
	EU: European Union
	IATA: International Air Transport Association
	IBC Code: International Code for the Construction and Equipment of Ships carrying
	Dangerous Chemicals in Bulk
	IMDG Code: International Maritime Dangerous Goods Code
	MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution
	from Ships
	OSHA: Occupational Safety and Health Administration
	PBT: Persistent, bioaccumulative and toxic
	PNEC: Predicted no-effect concentration
	REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
	RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
	vPvB: Very persistent and very bioaccumulative
	CNS: Central Nervous System
Reason of change:	General revision
Date of first version:	9/1/2008

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### Department issuing data sheet

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Contact person: see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

