

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Anti-D monoclonal, Anti-D Blend monoclonal

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

1.1. Product identifier

Anti-D monoclonal: Order-no. 67811, 678210, 678325
 Anti-D Blend monoclonal: Order-no. 6788, 678810, 678825

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

Use of the substance/mixture

Test reagents for use in the identification of the mentioned blood grouping antigens by the recommended techniques in the product inserts.

1.3. Details of the supplier of the safety data sheet

Company name: BAG Diagnostics GmbH
 Street: Amtsgerichtsstr. 1-5
 Place: D-35423 Lich
 Telephone: +49 (0)6404 925-100 Telefax: +49 (0)6404 925-460
 e-mail: info@bag-diagnostics.com
 Contact person: Dr. Evelyn Sachsenberg Telephone: +49 (0)6404 925-217
 e-mail: e.sachsenberg@bag-diagnostics.com
 Internet: www.bag-diagnostics.com

1.4. Emergency telephone number:

Extern: +49 (0)6131-19-240 Medizinische Klinik der Universität Mainz
 Intern: +49 (0)171-2157379

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.

2.2. Label elements

Regulation (EC) No. 1272/2008

Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Test reagents based on monoclonal antibodies.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
26628-22-8	sodium azide			< 0,1%
	247-852-1	011-004-00-7		
	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1; H300 H400 H410 EUH032			

Full text of H and EUH statements: see section 16.

Further Information

Sodium azide at a product concentration below 0,1 % by weight is not subject to labeling requirements

SECTION 4: First aid measures

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4.1. Description of first aid measures

After inhalation

Not applicable

After contact with skin

Wipe off affected area and flush with plenty of soap and water.

After contact with eyes

Immediately flush eyes with plenty of water the eyelids open.

After ingestion

Rinse mouth and drink plenty of water. In case of indisposition seek medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Select according to surrounding materials.

5.2. Special hazards arising from the substance or mixture

None

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact.

For personal protective equipment see heading 8.

6.3. Methods and material for containment and cleaning up

Collect spilled product with absorbing material (paper towels, cellulose), remove for disposal. Wipe the area until clean and dry.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

For In-Vitro-Diagnostic Use according to the instructions for use. Treatment as potentially infectious.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store in tightly closed containers at 2...8°C.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
26628-22-8	Sodium azide (as NaN ₃)	-	0.1		TWA (8 h)	WEL
		-	0.3		STEL (15 min)	WEL

8.2. Exposure controls

Protective and hygiene measures

The usual safety rules and precautionary measures for handling chemical and potentially infectious material must be adhered to. Protective work clothing should be worn. Do not eat or drink while working with the product. After working with the product, disinfect hands, wash hands carefully and remove protective work clothing.

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Eye/face protection

Not necessary

Hand protection

Disposable laboratory gloves

Respiratory protection

Not necessary

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid
 Colour: clear
 Odour: odourless

pH-Value (at 25 °C): 6,6 – 7,7

Changes in the physical state

Initial boiling point and boiling range: 100 °C
 Flash point: not applicable
 Lower explosion limits: not applicable
 Density: not available

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

Store below 2° C and/or above 8° C. Fire and excessive heat. Freezing and thawing may decompose the product.

10.5. Incompatible materials

Lead and Copper salt

10.6. Hazardous decomposition products

Sodium azide when heated to decomposition liberates nitrogen gas and sodium, which is explosive.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Toxicological dates for the products are not available. The product is classified according to Regulation (EC) No. 1272/2008 as not hazardous product.

CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	Source
26628-22-8	sodium azide				
	oral	ATE	5 mg/kg		

Further information

Nevertheless the product should be handled with the usual caution whilst handling biological products.

SECTION 12: Ecological information

12.1. Toxicity

Data regarding ecological effects of this product are not available. If handled and use appropriately, ecological

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problems are not expected to occur.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

In case there are residues to be disposed of (the quantities involved may only be a few Milliliters), these should be placed in disinfectant solution before disposal.

Contaminated packaging

Disposal is to be made in accordance with official local regulations.
Uncontaminated and completely emptied packaging may be treated as domestic waste or recycling.

SECTION 14: Transport information

Other applicable information

Cooled at +2... 8°C. No other special measures need be taken for transporting the products.

SECTION 15: Regulatory information

This MSDS meets the requirements of Regulation (EC) Nr. 1907/2006

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

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.
EUH210	Safety data sheet available on request.

Further Information

The information supplied here is based on data considered accurate and on current state of knowledge. No warranty is expressed or implied regarding the accuracy of this data. Liability is expressly disclaimed for loss or injury arising out of use of this information or the use of any materials designated. It does not establish any contractual relationship.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)