according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015 Revision date 01st August 2022 Version 6

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

Product identifier Monoclonal or polyclonal antibodies, proteins (including

lyophilized)

Substance / mixture mixture

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

Mixture's intended use

Monoclonal or polyclonal antibody, single antibody labeled with fluorochrome or cocktail of fluorescently labeled antibodies and proteins (including lyophilized) containing sodium azide as a preservative.

The use descriptors

SU 24 Scientific research and development

PC 21 Laboratory chemicals PROC 15 Use as laboratory reagent

Mixture uses advised against

The product should not be used in ways other then those referred in Section 1.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Name or trade name EXBIO Praha, a.s.

Address Nad Safinou II / 341, Vestec, 25250

> Czech Republic +420261090666 orders@exbio.cz

Phone F-mail Web address www.exbio.cz

Competent person responsible for the safety data sheet

EXBIO Praha, a.s. Name F-mail orders@exbio.cz

1.4. **Emergency telephone number**

European emergency number: 112

SECTION 2: Hazards identification

Classification of the substance or mixture

Classification of the mixture in accordance with Regulation (EC) No 1272/2008

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

Full text of all classifications and hazard statements is given in the section 16.

2.2. **Label elements**

none

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients

Mixtures

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	,	Acute Tox. 2, H300+H330 Acute Tox. 1, H310 STOT RE 2, H373 (ingestion) Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	1

according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015
Revision date 01st August 2022 Version

ion

6

Notes

1 Substance with a Union workplace exposure limit.

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

If inhaled

Possible irritation of airways, cough, headache.

If on skin

Not expected.

If in eyes

Possible irritation.

If swallowed

Nausea, stomach pain, vomiting, diarrhoea.

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

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015
Revision date 01st August 2022 Version 6

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

7.3. Specific end use(s)

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

European Union

Commission Directive 2000/39/EC

Substance name (component)	Туре	Value	Note	
	OEL 8 hours	0,1 mg/m ³		
sodium azide (CAS: 26628-22-8)	OEL 15 minutes	0,3 mg/m ³	Skin	

8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Protective goggles.

Skin protection

Hand protection: Protective gloves resistant to the product.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	not available
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	100 °C
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	soluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1 g/cm³ at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available

according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015 Revision date 01st August 2022

Version 6

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

The mixture is not reactive under normal conditions of use and storage. Sodium azide can react with metals contained in sewage to form lead or copper azide, which can explode on impact. When reacting with acids, sodium azide can release highly toxic hydrogen azide acid / hydrogen azide gas.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Sodium azide can react with metals contained in sewage to form lead or copper azide, which can explode on impact.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

sodium azide

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD50	27 mg/kg		Rat (Rattus norvegicus)	
Dermal	LD ₅₀	20 mg/kg		Rabbit	
Inhalation	LC50	0.054 mg/l	4 hour	Rat (Rattus norvegicus)	

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Based on available data the classification criteria are not met.

according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015
Revision date 01st August 2022 Version

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

6

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

sodium azide

Parameter	Value	Exposure time	Species	Environment
EC50	5.6 mg/l	48 hour	Aquatic invertebrates	

12.2. Persistence and degradability

not available

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1. UN number or ID number

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015 Revision date 01st August 2022

Version 6

SECTION 15: Regulatory information

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended.

15.2. Chemical safety assessment

not available

SECTION 16: Other information

A list of standard risk phrases used in the safety data sheet

H310 Fatal in contact with skin.

H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H300+H330 Fatal if swallowed or if inhaled.

A list of additional standard phrases used in the safety data sheet

EUH032 Contact with acids liberates very toxic gas.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR European agreement concerning the international carriage of dangerous goods by

road

BCF Bioconcentration Factor
CAS Chemical Abstracts Service

CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of

substance and mixtures

EC50 Concentration of a substance when it is affected 50% of the population EINECS European Inventory of Existing Commercial Chemical Substances

EmS Emergency plan

ES Identification code for each substance listed in EINECS

EU European Union

EuPCS European Product Categorisation System
IATA International Air Transport Association

IBC International Code For The Construction And Equipment of Ships Carrying

Dangerous Chemicals

ICAO International Civil Aviation Organization
IMDG International Maritime Dangerous Goods

INCI International Nomenclature of Cosmetic Ingredients
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry

LC50 Lethal concentration of a substance in which it can be expected death of 50% of the

population

LD50 Lethal dose of a substance in which it can be expected death of 50% of the

population

log Kow Octanol-water partition coefficient

MARPOL International Convention for the Prevention of Pollution from Ships

OEL Occupational Exposure Limits
PBT Persistent, Bioaccumulative and Toxic

ppm Parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID Agreement on the transport of dangerous goods by rail

according to Regulation (EC) No 1907/2006 (REACH) as amended

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 01st June 2015
Revision date 01st August 2022 Version 6

UN Four-figure identification number of the substance or article taken from the UN

Model Regulations

UVCB Substances of unknown or variable composition, complex reaction products or

biological materials

VOC Volatile organic compounds

vPvB Very Persistent and very Bioaccumulative

Acute Tox. Acute toxicity

Aquatic Acute Hazardous to the aquatic environment

Aquatic Chronic Hazardous to the aquatic environment (chronic)
STOT RE Specific target organ toxicity - repeated exposure

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

Overall revision of the safety data sheet according to Commission Regulation (EU) 2020/878.

More information

Classification procedure - calculation method.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.