

SAFETY DATA SHEET

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






T-cell BlastoFlowEx Kit

Date of creation	11th December 2017		
Date of revision	01st August 2022	Version	5

PRODUCT IDENTIFICATION

Cat. No.	Product name
ED7642	T-cell BlastoFlowEx Kit

COMPONENTS OF THE KIT

Code	Name	Classification
ED7642-1	Fix and Lysing Solution	 
ED7642-2	Permeabilizing Solution	 
ED7642-3	EDTA	
ED7642-4	CD3 APC/Ki-67 PE	Not classified as hazardous.

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date	11th December 2017	Version	5
Revision date	01st August 2022		

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

- 1.1. Product identifier**
Substance / mixture Fix and Lysing Solution
Number ED7642-1
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
diagnostic reagent
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 than 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
Phone +420261090666
E-mail orders@exbio.cz
Web address www.exbio.cz
Competent person responsible for the safety data sheet
Name EXBIO Praha, a.s.
E-mail orders@exbio.cz
- 1.4. Emergency telephone number**
European emergency number: 112

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is classified as dangerous.

Acute Tox. 4, H302
Skin Irrit. 2, H315
Skin Sens. 1, H317
Eye Irrit. 2, H319
STOT SE 3, H335
Muta. 2, H341
Carc. 1B, H350
STOT SE 2, H371
STOT RE 2, H373 (kidneys) (ingestion)

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

Most serious adverse effects on human health and the environment

May cause damage to the kidneys through prolonged or repeated exposure if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. May cause cancer. Suspected of causing genetic defects. May cause damage to organs. Harmful if swallowed.

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017
Revision date 01st August 2022 Version 5

2.2. Label elements

Hazard pictogram



Signal word

Danger

Hazardous substances

2,2'-oxybisethanol
formaldehyde
methanol

Hazard statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H371	May cause damage to organs.
H373	May cause damage to the kidneys through prolonged or repeated exposure if swallowed.

Precautionary statements

P201	Obtain special instructions before use.
P260	Do not breathe vapours.
P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P314	Get medical advice/attention if you feel unwell.

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

3.2. 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: 603-140-00-6 CAS: 111-46-6 EC: 203-872-2 Registration number: 01-2119457857-21-XXXX	2,2'-oxybisethanol	<30	Acute Tox. 4, H302 STOT RE 2, H373 (kidneys) (ingestion)	

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 605-001-00-5 CAS: 50-00-0 EC: 200-001-8	formaldehyde	<11	Acute Tox. 3, H301+H311+H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 Specific concentration limit: Skin Corr. 1B, H314: $C \geq 25\%$ Skin Irrit. 2, H315: $5\% \leq C < 25\%$ Skin Sens. 1, H317: $C \geq 0,2\%$ Eye Irrit. 2, H319: $5\% \leq C < 25\%$ STOT SE 3, H335: $C \geq 5\%$	1, 2, 4
Index: 603-001-00-X CAS: 67-56-1 EC: 200-659-6	methanol	<3	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1, H370 Specific concentration limit: STOT SE 1, H370: $C \geq 10\%$ STOT SE 2, H371: $3\% \leq C < 10\%$	3, 4

Notes

- Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
- Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".
- Substance with a Union workplace exposure limit.
- The use of the substance is restricted by Annex XVII of REACH Regulation

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 unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

If swallowed

Provide medical treatment. For persons with no symptoms, call the Toxicological Information Centre to decide about the need of medical treatment; provide information about the substances or composition of the product from the original packaging or the Safety Data Sheet of the product.

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

If inhaled

Cough, headache. May cause respiratory irritation.

If on skin

May cause an allergic skin reaction.

If in eyes

Causes serious eye irritation.

If swallowed

Irritation, nausea.

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 a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes.

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. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Obtain special instructions before use. Do not eat, drink or smoke when using this product. Wash hands and exposed parts of the body thoroughly after handling. Do not handle until all safety precautions have been read and understood. Use only outdoors or in a well-ventilated area. 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. Store locked up. Keep container tightly closed.

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017
Revision date 01st August 2022 Version 5

7.3. Specific end use(s)

diagnostic reagent

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 2006/15/EC

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	260 mg/m ³	Skin
	OEL 8 hours	200 ppm	

8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. 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. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

Respiratory protection

Halfmask with a filter against organic vapours or a self-contained breathing apparatus as appropriate if exposure limit values of substances are exceeded or in a poorly ventilated environment.

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	colourless
Odour	characteristic, sweet / pungent
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
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	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

SECTION 10: Stability and reactivity

10.1. Reactivity

not available

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

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

May cause damage to organs. Harmful if swallowed.

2,2'-oxybisethanol

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Skin	LD ₅₀	11890 mg/kg		Rabbit	

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Suspected of causing genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

May cause respiratory irritation. May cause damage to organs.

Toxicity for specific target organ - repeated exposure

May cause damage to the kidneys through prolonged or repeated exposure if swallowed.

Aspiration hazard

Based on available data the classification criteria are not met.

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.

SECTION 12: Ecological information

12.1. Toxicity

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

Acute toxicity

2,2'-oxybisethanol

Parameter	Value	Exposure time	Species	Environment
LC ₅₀	75.2 mg/kg	96 hour	Fishes (Pimephales promelas)	

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

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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.

Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

formaldehyde

Restriction	Conditions of restriction
28	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: <ul style="list-style-type: none"> — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>"Restricted to professional users".</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: <ul style="list-style-type: none"> — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. (f) devices covered by Regulation (EU) 2017/745.

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

formaldehyde

Restriction	Conditions of restriction
72	<p>1. Shall not be placed on the market after 1 November 2020 in any of the following:</p> <p>(a) clothing or related accessories;</p> <p>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;</p> <p>(c) footwear;</p> <p>if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12.</p> <p>2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter.</p> <p>3. Paragraph 1 shall not apply to:</p> <p>(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;</p> <p>(b) non-textile fasteners and non-textile decorative attachments;</p> <p>(c) second-hand clothing, related accessories, textiles other than clothing or footwear</p> <p>(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.</p> <p>4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**).</p> <p>5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.</p> <p>6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.</p> <p>7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.</p> <p>(*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).</p> <p>(**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).</p>

methanol

Restriction	Conditions of restriction
69	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.

15.2. Chemical safety assessment

not available

SECTION 16: Other information

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

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date	11th December 2017	Version	5
Revision date	01st August 2022		

H341	Suspected of causing genetic defects.
H350	May cause cancer.
H370	Causes damage to organs.
H371	May cause damage to organs.
H373	May cause damage to the kidneys through prolonged or repeated exposure if swallowed.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.

Guidelines for safe handling used in the safety data sheet

P201	Obtain special instructions before use.
P260	Do not breathe vapours.
P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P314	Get medical advice/attention if you feel unwell.

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
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
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	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
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

SAFETY DATA SHEET

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

Fix and Lysing Solution

Creation date	11th December 2017	Version	5
Revision date	01st August 2022		

Carc.	Carcinogenicity
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
Muta.	Germ cell mutagenicity
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization
STOT RE	Specific target organ toxicity - repeated exposure
STOT SE	Specific target organ toxicity - single 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.

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date	11th December 2017		
Revision date	01st August 2022	Version	5

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- 1.1. Product identifier**
Substance / mixture Permeabilizing Solution
Number ED7642-2
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
diagnostic reagent
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 than 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
Phone +420261090666
E-mail orders@exbio.cz
Web address www.exbio.cz
Competent person responsible for the safety data sheet
Name EXBIO Praha, a.s.
E-mail orders@exbio.cz
- 1.4. Emergency telephone number**
European emergency number: 112

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is classified as dangerous.

Acute Tox. 4, H302
Skin Irrit. 2, H315
Skin Sens. 1, H317
Eye Irrit. 2, H319
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Muta. 2, H341
Carc. 1B, H350
STOT SE 2, H371
STOT RE 2, H373 (kidneys) (ingestion)

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

Most serious adverse effects on human health and the environment

May cause damage to the kidneys through prolonged or repeated exposure if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. May cause cancer. Suspected of causing genetic defects. May cause damage to organs. Harmful if swallowed.

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017
Revision date 01st August 2022 Version 5

2.2. Label elements

Hazard pictogram



Signal word

Danger

Hazardous substances

2,2'-oxybisethanol
formaldehyde
methanol

Hazard statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H371	May cause damage to organs.
H373	May cause damage to the kidneys through prolonged or repeated exposure if swallowed.

Precautionary statements

P201	Obtain special instructions before use.
P260	Do not breathe vapours.
P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P314	Get medical advice/attention if you feel unwell.

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

3.2. 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: 603-140-00-6 CAS: 111-46-6 EC: 203-872-2 Registration number: 01-2119457857-21-XXXX	2,2'-oxybisethanol	<30	Acute Tox. 4, H302 STOT RE 2, H373 (kidneys) (ingestion)	

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 605-001-00-5 CAS: 50-00-0 EC: 200-001-8	formaldehyde	<11	Acute Tox. 3, H301+H311+H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 Specific concentration limit: Skin Corr. 1B, H314: $C \geq 25\%$ Skin Irrit. 2, H315: $5\% \leq C < 25\%$ Skin Sens. 1, H317: $C \geq 0,2\%$ Eye Irrit. 2, H319: $5\% \leq C < 25\%$ STOT SE 3, H335: $C \geq 5\%$	1, 2, 4
Index: 603-001-00-X CAS: 67-56-1 EC: 200-659-6	methanol	<3	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1, H370 Specific concentration limit: STOT SE 1, H370: $C \geq 10\%$ STOT SE 2, H371: $3\% \leq C < 10\%$	3, 4

Notes

- Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
- Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".
- Substance with a Union workplace exposure limit.
- The use of the substance is restricted by Annex XVII of REACH Regulation

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 unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

If swallowed

Provide medical treatment. For persons with no symptoms, call the Toxicological Information Centre to decide about the need of medical treatment; provide information about the substances or composition of the product from the original packaging or the Safety Data Sheet of the product.

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

If inhaled

Cough, headache. May cause respiratory irritation.

If on skin

May cause an allergic skin reaction.

If in eyes

Causes serious eye irritation.

If swallowed

Irritation, nausea.

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 a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes.

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. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Obtain special instructions before use. Do not eat, drink or smoke when using this product. Wash hands and exposed parts of the body thoroughly after handling. Do not handle until all safety precautions have been read and understood. Use only outdoors or in a well-ventilated area. 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. Store locked up. Keep container tightly closed.

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017
Revision date 01st August 2022 Version 5

7.3. Specific end use(s)

diagnostic reagent

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 2006/15/EC

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	260 mg/m ³	Skin
	OEL 8 hours	200 ppm	

8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. 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. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

Respiratory protection

Halfmask with a filter against organic vapours or a self-contained breathing apparatus as appropriate if exposure limit values of substances are exceeded or in a poorly ventilated environment.

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	colourless
Odour	characteristic, sweet / pungent
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
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	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

SECTION 10: Stability and reactivity

10.1. Reactivity

not available

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

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

May cause damage to organs. Harmful if swallowed.

2,2'-oxybisethanol

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Skin	LD ₅₀	11890 mg/kg		Rabbit	

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Suspected of causing genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

May cause respiratory irritation. May cause damage to organs.

Toxicity for specific target organ - repeated exposure

May cause damage to the kidneys through prolonged or repeated exposure if swallowed.

Aspiration hazard

Based on available data the classification criteria are not met.

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.

SECTION 12: Ecological information

12.1. Toxicity

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

Acute toxicity

2,2'-oxybisethanol

Parameter	Value	Exposure time	Species	Environment
LC ₅₀	75.2 mg/kg	96 hour	Fishes (Pimephales promelas)	

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

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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.

Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

formaldehyde

Restriction	Conditions of restriction
28	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than: <ul style="list-style-type: none"> — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>"Restricted to professional users".</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: <ul style="list-style-type: none"> — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date. (f) devices covered by Regulation (EU) 2017/745.

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

formaldehyde

Restriction	Conditions of restriction
72	<p>1. Shall not be placed on the market after 1 November 2020 in any of the following:</p> <p>(a) clothing or related accessories;</p> <p>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;</p> <p>(c) footwear;</p> <p>if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12.</p> <p>2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter.</p> <p>3. Paragraph 1 shall not apply to:</p> <p>(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;</p> <p>(b) non-textile fasteners and non-textile decorative attachments;</p> <p>(c) second-hand clothing, related accessories, textiles other than clothing or footwear</p> <p>(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.</p> <p>4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**).</p> <p>5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.</p> <p>6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.</p> <p>7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.</p> <p>(*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).</p> <p>(**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).</p>

methanol

Restriction	Conditions of restriction
69	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.

15.2. Chemical safety assessment

not available

SECTION 16: Other information

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

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date	11th December 2017	Version	5
Revision date	01st August 2022		

H341	Suspected of causing genetic defects.
H350	May cause cancer.
H370	Causes damage to organs.
H371	May cause damage to organs.
H373	May cause damage to the kidneys through prolonged or repeated exposure if swallowed.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.

Guidelines for safe handling used in the safety data sheet

P201	Obtain special instructions before use.
P260	Do not breathe vapours.
P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P314	Get medical advice/attention if you feel unwell.

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
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
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	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
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
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SAFETY DATA SHEET

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

Permeabilizing Solution

Creation date	11th December 2017		
Revision date	01st August 2022	Version	5

Carc.	Carcinogenicity
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
Muta.	Germ cell mutagenicity
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization
STOT RE	Specific target organ toxicity - repeated exposure
STOT SE	Specific target organ toxicity - single 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.

SAFETY DATA SHEET

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

EDTA

Creation date	11th December 2017		
Revision date	01st August 2022	Version	5

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

- 1.1. Product identifier**
Substance / mixture EDTA
Number ED7642-3
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
diagnostic reagent
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 than 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
Phone +420261090666
E-mail orders@exbio.cz
Web address www.exbio.cz
Competent person responsible for the safety data sheet
Name EXBIO Praha, a.s.
E-mail orders@exbio.cz
- 1.4. Emergency telephone number**
European emergency number: 112

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008
The mixture is classified as dangerous.

STOT RE 2, H373

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

Most serious adverse effects on human health and the environment

May cause damage to organs through prolonged or repeated exposure.

- 2.2. Label elements**
Hazard pictogram



Signal word
Warning

Hazardous substances

Ethylenediaminetetraacetic acid-Na₂-salt-2H₂O

Hazard statements

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

Precautionary statements

P260 Do not breathe vapours.

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017
Revision date 01st August 2022 Version 5

P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container to by handing over to the person authorized to dispose of waste or by returning to the supplier.

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

3.2. 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
CAS: 6381-92-6 EC: 205-358-3 Registration number: 01-2119486775-20	Ethylenediaminetetraacetic acid-Na ₂ -salt-2H ₂ O	<15	Acute Tox. 4, H332 STOT RE 2, H373	
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	<0.099	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

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 unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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. Rinsing should continue at least for 10 minutes.

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

Cough, headache.

If on skin

Not expected.

If in eyes

Possible irritation.

If swallowed

Irritation, nausea.

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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 a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. 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. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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)

diagnostic reagent

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

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. 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. Contaminated skin should be washed thoroughly.

Respiratory protection

Mask with a filter in a poorly ventilated environment.

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	colourless
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
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	data not available
Relative vapour density	data not available
Particle characteristics	data not available

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.

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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.

Ethylenediaminetetraacetic acid-Na₂-salt-2H₂O

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Inhalation (dust/mist)	LC ₅₀	5 mg/l	4 hour		

sodium azide

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD ₅₀	27 mg/kg		Rat (Rattus norvegicus)	
Dermal	LD ₅₀	20 mg/kg		Rabbit	
Inhalation	LC ₅₀	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

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

Based on available data the classification criteria are not met.

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.

SECTION 12: Ecological information

12.1. Toxicity

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

Acute toxicity

Ethylenediaminetetraacetic acid-Na₂-salt-2H₂O

Parameter	Value	Exposure time	Species	Environment
LC ₅₀	320 mg/l	96 hour	Fishes (Poecilia reticulata)	

sodium azide

Parameter	Value	Exposure time	Species	Environment
EC ₅₀	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

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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.
H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
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.

Guidelines for safe handling used in the safety data sheet

P260	Do not breathe vapours.
P314	Get medical advice/attention if you feel unwell.
P501	Dispose of contents/container to by handing over to the person authorized to dispose of waste or by returning to the supplier.

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

EUH032	Contact with acids liberates very toxic gas.
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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
EC ₅₀	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
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	Octanol-water partition coefficient

SAFETY DATA SHEET

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

EDTA

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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
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.

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date 11th December 2017
Revision date 01st August 2022 Version 5

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

- 1.1. Product identifier** CD3 APC/Ki-67 PE
Substance / mixture mixture
Number ED7642-4
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
diagnostic reagent
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 than 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
Phone +420261090666
E-mail orders@exbio.cz
Web address www.exbio.cz
Competent person responsible for the safety data sheet
Name EXBIO Praha, a.s.
E-mail orders@exbio.cz
- 1.4. Emergency telephone number**
European emergency number: 112

SECTION 2: Hazards identification

- 2.1. 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

- 3.2. 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	<0,099	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

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date	11th December 2017		
Revision date	01st August 2022	Version	5

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.

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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)

diagnostic reagent

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

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	colourless
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	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1 g/cm ³ at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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	LD ₅₀	27 mg/kg		Rat (Rattus norvegicus)	
Dermal	LD ₅₀	20 mg/kg		Rabbit	
Inhalation	LC ₅₀	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.

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

sodium azide

Parameter	Value	Exposure time	Species	Environment
EC ₅₀	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

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date 11th December 2017

Revision date 01st August 2022

Version

5

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.
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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
EC ₅₀	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
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	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

SAFETY DATA SHEET

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

CD3 APC/Ki-67 PE

Creation date	11th December 2017		
Revision date	01st August 2022	Version	5

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.