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www.biovendor.com

SAFETY INFORMATION

Product name:	me: epicGEN Solid Cancer & MSI Kit	
Catalogue number: RDEG0001		
Characteristics: Product for preparation of NGS sequencing libraries.		
Intended use:	For research use only. Users should have a thorough understanding of the IFU prior	
	to their use of this kit.	

Manufacturer:	BioVendor – Laboratorní medicína a.s.
Registered office: Karásek 1767/1, 621 00 Brno, Czech Republic	
Company ID:	63471507

Kit Components	Contents hazardous substance
epicGEN Fragmentation Buffer	No
epicGEN Fragmentation Enhancer	No
epicGEN Fragmentation Enzyme	No
epicGEN Ligation Buffer	No
epicGEN Ligation Enzyme	No
epicGEN Adaptors	No
epicGEN PCR1 Master Mix	Tetramethylammonium chloride 1–5%
epicGEN UDI primers	No
TE Buffer	No
epicGEN Hybridization Buffer	Tetramethylammonium chloride 10–30%
epicGEN Hybridization Buffer Enhancer	Formamide ≤100%
epicGEN Blockers TruSeq	No
epicGEN Solid cancer & MSI panel	No
epicGEN 2X Bead Wash Buffer	No
epicGEN 10X Wash Buffer 1	No
epicGEN 10X Wash Buffer 2	No
epicGEN 10X Wash Buffer 3	No
epicGEN 10X Stringent Wash Buffer	No
epicGEN Human Cot DNA	No
epicGEN Streptavidin Beads	No
epicGEN PCR2 Master Mix	No
epicGEN Primer Mix	No

Safety Data Sheets in accordance with the current (EC/EU) Regulations as amended are attached.

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SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: epicGEN PCR1 Master Mix

UFI: Not apply.

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

No use descriptors (LCS, SU, PC, PROC, ERC, AC, TF categories) of the substance or mixture are available

Application of the substance / the mixture:

Reagent solution intended for laboratory use. Used to prepare sequencing libraries for next-generation sequencing (NGS).

For research use only.

Uses advised against: Not intended for diagnostic or therapeutic purposes in humans or animals.

1.3 Details of the supplier of the safety data sheet

BioVendor – Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: info@biovendor.com Web: www.biovendor.com

Further information obtainable from:

Ing. Karel Královec

Studio2K Czech Republic

Phone: +420 777 145 808 E-mail: bl@studio2k.cz

Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

European Chemicals Agency. National helpdesks contact details:

https://echa.europa.eu/support/helpdesks

Links to Poison Centers and Clinical Toxicologists all over the World:

https://www.eapcct.org/index.php?page=links

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is classified as dangerous in the terms of the Regulation (EC) No 1272/2008 (CLP).

Acute Tox. 4 H302 Harmful if swallowed.

STOT SE 2 H371 May cause damage to the central nervous system.

Route of exposure: Oral.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.

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Hazard pictograms:



Signal word: Warning

Hazard-determining components of labelling: tetramethylammonium chloride

Hazard statements:

H302 Fatal if swallowed.

H371 May cause damage to the central nervous system. Route of exposure: Oral.

Precautionary statements:

P260 Do not breathe vapours/spray.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P308+P311 If exposed or concerned: Call a POISON CENTER/doctor.

P405 Store locked up.

P501 Dispose of contents/container to an approved waste disposal facility.

Additional information: Void.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms:



Signal word: Warning

Hazard-determining components of labelling: tetramethylammonium chloride

Hazard statements: Void.

Classification system: The product is intended for professional use only and this corresponds to its labeling on the packaging.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

vPvB:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as vPvB according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

Determination of endocrine-disrupting properties

The mixture does not contain substances that have been identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

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SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components	Classification	Concentrati on
CAS: 75-57-0 EINECS: 200-880-8	tetramethylammonium chloride	1–5 %
REACH:01-2119970924-26-XXXX	Acute Tox. 2, H300; Acute Tox. 3, H311 STOT SE 1, H370 Aquatic Chronic 2, H411 Skin Irrit. 2, H315	

Non dangerous components	Classification	Concentration
CAS: 56-81-5 EINECS: 200-289-5 REACH: 01-2119471987-18-XXXX	glycerol	10–30%

SVHC: The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).

Regulation (EC) No 648/2004 on detergents / Labelling for contents: Not apply.

Additional information:

The substances named in this section are given with their actual, appropriate classification! For substances that are listed in appendix VI, table 3 of the Regulation (EC) No 1272/2008 (CLP Regulation) this means that all notes that may be given here for the named classification have been taken into account.

For the wording of the listed hazard phrases refer to section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information:

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

Never pour anything into the mouth of an unconscious person!

Personal protection for the First Aider.

Immediately remove any clothing soiled by the product.

After inhalation:

Remove person from danger area.

Take care of fresh air supply and seek medical assistance upon subsequent or lasting problems.

After skin contact:

Wash the affected skin with plenty of water. Upon skin irritation or other problems, consult further procedure with an expert physician.

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After eye contact:

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water for a period of several minutes. In case of eye irritation or other difficulties, consult further procedure with an ophthalmologist.

After swallowing:

Thoroughly rinse the mouth with water and do not cause vomiting. Put the affected person in warm and calm conditions. Seek medical assistance immediately.

Information for doctor: Symptomatic treatment.

4.2 Most important symptoms and effects, both acute and delayed

Possible toxicological effects resulting from the classification are stated in Section 11.

Upon inhalation:

Narcotic effects.

Respiratory tract irritation.

Discomfort and vomiting.

Muscle pain.

After skin contact:

Pains.

In case of eye contact:

Mild irritation.

Upon ingestion:

Stomach pain.

Vomiting and diarrhea.

4.3 Indication of any immediate medical attention and special treatment needed

In case of ingestion or affecting of eyes, seek medical help immediately.

For special medical advice, contact the Toxicology Information Centre.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents:

The product itself is not flammable.

Alcohol resistant foam, carbon dioxide (CO₂), water spray or water mist, extinguishing powder. Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents: Water with full jet.

5.2 Special hazards arising from the substance or mixture

Formation of irritating, toxic and harmful fumes of burning is possible in case of fire.

Possibly they may be released:

Highly toxic and corrosive gases or vapours.

Inhalation of hazardous decomposition products of burning may result in damaged health.

5.3 Advice for firefighters

Protective equipment:

Do not inhale explosion gases or combustion gases.

According to size of fire.

Corresponding protective insulation breathing apparatus and overpressure counter-chemical protective clothing.

5.4 Further information

Cool with water the products in enclosed packaging, which is near the fire.

If possible, remove the products in un-damaged packaging from the danger area.

Store the contaminated extinguishing water separately and do not let it into the sewerage.

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Remove the extinguishing water or used extinguishing materials together with the remnants of the fire according to the corresponding regulations.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Respect the instructions set forth in Sections 7 and 8 of the safety data sheet.

For non-emergency personnel:

In case of spillage or accidental release, wear personal protective equipment as specified in section 8 to prevent contamination.

Leave the danger zone if possible, use existing emergency plans if necessary.

Ensure adequate ventilation.

Use personal protective equipment.

Avoid contact with eyes and skin.

Prevent the possibility of slipping on the spilled product.

Prevent entry of unauthorized and unprotected persons.

For emergency responders:

See section 8 for suitable protective equipment and material specification

6.2 Environmental precautions

The product is classified as dangerous for the environment.

Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and place into suitable and marked vessels.

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.

Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

In addition to the information provided in this section, important information is also provided in Sections 6 and 8.

Information about fire - and explosion protection:

No special measures required.

Respect general regulations on fire prevention.

Handling:

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet. Ensure good ventilation.

Prevent formation of aerosols.

Use personal protective equipment.

Avoid contact with eyes and skin.

Avoid long-term or intense skin contact.

Use working methods according to operating instructions.

Observe directions on label and instructions for use.

General hygiene measures for the handing of chemicals are applicable.

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Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.

Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

Do not eat, drink, smoke, or snuff during use.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Secure impermeable floors against the liquids.

Store only in unopened original receptacles.

Vessels already open must be reclosed carefully and stored in the upright position in order to prevent leakage of the contents.

Information about storage in one common storage facility:

Keep away from food, drink and animal feedingstuffs.

Further information about storage conditions:

Store in a well ventilated place.

Store in a dry and cool place.

Keep containers tightly sealed.

Protect from exposure to the light.

Protect containers from physical damage.

Store under lock and key and with access restricted to technical experts or their assistants only. Keep out of reach of children.

7.3 Specific end use(s)

The product is intended only for professional use.

Specific use is stated in the manual for use on the product packaging label or in the product documentation.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs:			
56-81-5 glycerol			
Oral	DNEL – Long term exposure, systemic effects	229 mg/kg/d (consumers)	
Inhalativa	DNEL Long term expecure local effects	33 mg/m³ (consumers)	
mnaiative	DNEL – Long term exposure, local effects	56 mg/m³ (workers)	
PNECs:	PNECs:		
56-81-5 glycerol			
PNEC - F	PNEC – Freshwater 0.885 mg/l		
PNEC – Marine water 0.08		0.088 mg/l	
PNEC – Sewage treatment plant 1,000 mg/l		1,000 mg/l	
PNEC – Sediment, freshwater 3.3 mg/kg			
PNEC – Sediment, marine water 0.33 mg/kg		0.33 mg/kg	
PNEC – Soil 0.141 mg/kg		0.141 mg/kg	
PNEC - W	PNEC – Water (sporadic release) 8.85 mg/l		

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Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with biological limit values.

8.2 Exposure controls

Appropriate engineering controls:

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under WEL or IOEL values, suitable breathing protection should be worm. Applies only if maximum permissible exposure values are listed here.

Individual protection measures, such as personal protective equipment General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat, drink, smoke or sniff while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Do not inhale gases/fumes/aerosols.

Avoid contact with the eyes and skin.

8.2.1 Personal protective equipment

a) Eye/face protection:



Not required during regular use.

Alternatively, use closed safety glasses (EN 166).

b) Skin protection



Body protection

As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.

When handling laboratory scale quantities, a lab coat is recommended.



Hand protection

Protective gloves (EN ISO 374-1).

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Preventive skin protection by use of skin-protecting agents is recommended.

Material of gloves:

Not determined.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:

Not determined.

No tests have been performed, glove resistance must be tested before use.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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c) Respiratory protection:



Unnecessary during regular use.

In case of insufficient ventilation and exceeding permitted exposure limits, use a suitable half-mask (EN 149+A1) with a filter (EN 14387+A1).

Observe wearing time limitations for respiratory protection equipment.

Recommended filter device for short term use:

Not determined.

d) Thermal hazards:

Not applicable.

8.3 Environmental exposure controls

Adhere to usual measures for environmental protection, see Section 6.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

General Information

Physical state:

Colour:

Odour:

Melting point/freezing point:

Boiling point or initial boiling point and boiling range:

Liquid.

Colourless.

Not determined

Not determined.

Flammability: Not classified as a flammability

hazard.

Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Auto-ignition temperature: Not determined.
Decomposition temperature: Not determined.

pH: 8.7

Viscosity

Kinematic viscosity: Not determined. Dynamic viscosity: Not determined.

Solubility in water: Miscible.

Partition coefficient n-octanol/water (log value): Not determined. Vapour pressure: Not determined.

Density and/or relative density

Density: Not determined.
Relative density: Not determined.
Vapour density: Not determined.
Relative gas density: Not determined.

9.2 Other information

Important information on protection of health and environment, and on safety.

Ignition temperature: Not determined.

Explosive properties: Product does not present an

explosion hazard.

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Solvent content

VOC (2010/75/EC):

Oxidising properties:

Evaporation rate:

Relative evaporation rate:

Not determined.

Not determined.

Not determined.

Information with regard to physical hazard classes

Explosives: Void. Flammable gases: Void. Aerosols: Void. Oxidising gases: Void. Gases under pressure: Void. Flammable liquids: Void. Flammable solids: Void. Self-reactive substances and mixtures: Void. Pyrophoric liquids: Void. Pyrophoric solids: Void. Self-heating substances and mixtures: Void.

Substances and mixtures, which emit flammable gases

in contact with water:

Oxidising liquids:

Oxidising solids:

Organic peroxides:

Corrosive to metals:

Desensitised explosives:

Void.

Void.

Void.

Void.

Additional information: No relevant information available.

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.2 Chemical stability

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.3 Possibility of hazardous reactions

No dangerous reactions known

10.4 Conditions to avoid

Protect against high temperatures.

Protect against direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

Poisonous gases/vapours

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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

Acute toxicity: Harmful if swallowed.

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Relevant toxicological values for classification:			
Oral	ATE	500 mg/kg	
Dermal	ATE	53,700 mg/kg	
75-57-0 tetramethylammonium chloride			
Oral	LD50	47 mg/kg (rat) (OECD 401 - Acute Oral Toxicity)	
Dermal	LD50	> 200–500 mg/kg (rabbit) (OECD 402 - Acute Dermal Toxicity)	

Primary irritant effect

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.

STOT-single exposure:

May cause damage to the central nervous system. Route of exposure: Oral.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional toxicological information:

No relevant information is available.

Acute effects:

Acute oral toxicity, Hazard category 4.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

No CMR effects are known.

11.2 Additional Information

Endocrine disrupting properties:

None of the ingredients is listed.

Other information: No other relevant information available on adverse effects on health.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

Based on available data, the classification criteria are not met.

75-57-0 tetramethylammonium chloride		
LC50/96 h	462 mg/l (fish) (OECD 203 - Fish, Acute Toxicity Test) Pimephales promelas	
NOEC/11 d	0.03 mg/l (daphnia) Daphnia magna	

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12.2 Persistence and degradability

No further relevant information available.

Behaviour in waste water treatment plants:

No relevant information is available.

12.3 Bioaccumulative potential

56-81-5 glycerol			
log Dow	-1.75		
log Pow	bioaccumulation is not expected		

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

The product does not contain substances classified as PBT or vPvB and included in the list of substances subject to authorization (Annex XIV of EP and R Regulation No 1907/2006, as amended).

PBT: No relevant information is available.

vPvB: No relevant information is available.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information

AOX-indication: No relevant information is available.

General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even extremely small quantities leak into the ground.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Recommendation:

Must not be disposed together with household waste. Do not allow product to reach sewage system.

Remove product residues according to the corresponding local directives in the adequate equipment as hazardous waste. E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

Waste disposal key:

The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances (2001/118/EC, 2001/119/EC, 2001/573/EC, 2014/955/EU).

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European waste catalogue and hazardous properties of waste:			
18 01 06*	chemicals consisting of or containing hazardous substances		
15 01 10*	packaging containing residues of or contaminated by hazardous substances		
15 01 02	plastic packaging		
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity		
HP6	Acute Toxicity		

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be reused.

Non contaminated packagings may be recycled.

Dispose of packaging that cannot be cleaned in the same manner as the mixture.

Empty container completely.

Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Hand over possible empty packaging to an authorised organisation, which is entitled to their disposal.

Recommended cleansing agents:

Water, if necessary together with cleansing agents.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council. Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number

ADR, IMDG, IATA: Void.

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA: Void.

14.3 Transport hazard class(es)

ADR. ADN. IMDG. IATA

Class: Void.

14.4 Packaging group

ADR/RID, IMDG, IATA: Void

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Unless specified otherwise, general measures for safe transport must be followed.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

Transport/Additional information: Non-dangerous material according to Transport Regulations. **UN "Model Regulation":** Void.

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SECTION 15 REGULATORY INFORMATION

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

Directive 2004/42/EC of the European Parliament and the Council: Does not apply.

Named dangerous substances - ANNEX I: None of the ingredients is listed.

REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II:

None of the ingredients is listed.

REGULATION (EU) 2019/1148:

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors:

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors:

None of the ingredients is listed.

Legal regulations of the European Community:

Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), applicable as from 1 January 2025.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, as amended.

COMMISSION REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: 2016/918 (8. ATP from 1.2.2018), 2016/1179 (9. ATP from 1.3.2018), 2017/776 (10. ATP from 1.12.2018), 2018/669 (11. ATP from 1.12.2019), 2019/521 (12. ATP from 17.10.2020), 2018/1480 (13. ATP from 1.5.2020). COMMISSION DELEGATED REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures:

2020/217 (14. ATP from 1.10.2021), 2020/1182 (15. ATP from 1.3.2022), 2021/643 (16. ATP from 10.5.2021), 2021/849 (17. ATP from 17.12.2022), 2022/692 (18. ATP from 1.12.2023), 2023/1434 (19. ATP from 1.8.2023), 2023/1435 (20. ATP from 1.2.2025).

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15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Warning:

The safety data sheet contains data needed for securing safety and health protection during work and environ-mental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

Relevant phrases:

H300 Fatal if swallowed.
H311 Toxic in contact with skin.
H315 Causes skin irritation.
H370 Causes damage to organs.

H411 Toxic to aquatic life with long lasting effects.

Training hints:

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other ex-pert documents for the product, issued by the supplier.

Recommended restriction of use:

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about the work procedures, hazardous properties of the product, and also about the necessary safety measures.

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to ad-here to the product usage conditions and to respect the safety instructions for health and environmental protection.

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.

Classification according to Regulation (EC) No 1272/2008:		
Acute toxicity - oral	Calculation method	
Specific target organ toxicity (single exposure)		

First issue of SDS: 05.11.2025 Documents used to prepare SDS:

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par

route (European Agreement Concerning the International Carriage of

Dangerous Goods by Road)

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IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, ioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1
STOT SE 2: Specific target organ toxicity (single exposure) – Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard -

Category 2

Information on data sources used in compiling the safety data sheet:

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2020/878 of 18 June 2020.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

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SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: epicGEN Hybridization Buffer

UFI: Not apply.

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

No use descriptors (LCS, SU, PC, PROC, ERC, AC, TF categories) of the substance or mixture are available

Application of the substance / the mixture:

Reagent solution intended for laboratory use. Used to prepare sequencing libraries for next-generation sequencing (NGS).

For research use only.

Uses advised against: Not intended for diagnostic or therapeutic purposes in humans or animals.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: <u>info@biovendor.com</u> Web: <u>www.biovendor.com</u>

Further information obtainable from:

Ing. Karel Královec

Studio2K

Czech Republic

Phone: +420 777 145 808 E-mail: bl@studio2k.cz

Website: www.bezpecnostni-listy.eu

1.4 Emergency telephone number

European Chemicals Agency. National helpdesks contact details:

https://echa.europa.eu/support/helpdesks

Links to Poison Centers and Clinical Toxicologists all over the World:

https://www.eapcct.org/index.php?page=links

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is classified as dangerous in the terms of the Regulation (EC) No 1272/2008 (CLP).

Acute Tox. 2 H300 Fatal if swallowed.
Skin Irrit. 2 H315 Causes skin irritation.

STOT SE 1 H370 Causes damage to the central nervous system.

Route of exposure: Oral.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

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2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.

Hazard pictograms:



Signal word: Danger

Hazard-determining components of labelling: tetramethylammonium chloride

Hazard statements:

H300 Fatal if swallowed. H315 Causes skin irritation.

H370 Causes damage to the central nervous system. Route of exposure: Oral.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P260 Do not breathe vapours/spray.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see medical advice on this label).

P330 Rinse mouth.

P302+P352 IF ON SKIN: Wash with plenty of water.

P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor. P362+P364 Take off contaminated clothing and wash it before reuse. P332+P313 If skin irritation occurs: Get medical advice/attention.

P391 Collect spillage. P405 Store locked up.

P501 Dispose of contents/container to an approved waste disposal facility.

Additional information: Void.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms:



Signal word: Danger

Hazard-determining components of labelling: tetramethylammonium chloride

Hazard statements:

H300 Fatal if swallowed.

H370 Causes damage to the central nervous system. Route of exposure: Oral.

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Precautionary statements:

P260 Do not breathe vapours/spray.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see medical advice on this label).

P330 Rinse mouth.

P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor.

P405 Store locked up.

P501 Dispose of contents/container to an approved waste disposal facility.

Classification system: The product is intended for professional use only and this corresponds to its labelling on the packaging.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

vPvB:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as vPvB according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

Determination of endocrine-disrupting properties

The mixture does not contain substances that have been identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components	Classification	Concentration
CAS: 75-57-0 EINECS: 200-880-8	tetramethylammonium chloride	10–30 %
REACH:01-2119970924-26-XXXX	Acute Tox. 2, H300; Acute Tox. 3, H311 STOT SE 1, H370 Aquatic Chronic 2, H411 Skin Irrit. 2, H315	

SVHC: The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).

Regulation (EC) No 648/2004 on detergents / Labelling for contents: Not apply.

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Additional information:

The substances named in this section are given with their actual, appropriate classification! For substances that are listed in appendix VI, table 3 of the Regulation (EC) No 1272/2008 (CLP Regulation) this means that all notes that may be given here for the named classification have been taken into account.

For the wording of the listed hazard phrases refer to section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information:

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

Never pour anything into the mouth of an unconscious person!

Personal protection for the First Aider.

Immediately remove any clothing soiled by the product.

After inhalation:

Remove person from danger area.

Take care of fresh air supply and seek medical assistance upon subsequent or lasting problems.

After skin contact:

Wash the affected skin with plenty of water. Upon skin irritation or other problems, consult further procedure with an expert physician.

After eye contact:

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water for a period of several minutes. In case of eye irritation or other difficulties, consult further procedure with an ophthalmologist.

After swallowing:

Thoroughly rinse the mouth with water, have the affected person drink 1 to 2 glasses of water and do not induce vomiting. Seek medical assistance immediately.

Information for doctor: Symptomatic treatment.

4.2 Most important symptoms and effects, both acute and delayed

Possible toxicological effects resulting from the classification are stated in Section 11.

Upon inhalation:

Narcotic effects.

Respiratory tract irritation.

Discomfort and vomiting.

Muscle pain.

After skin contact:

Skin irritation.

Reddening of the skin.

In case of eye contact:

Mild irritation.

Upon ingestion:

Unconsciousness.

Death.

Stomach pain.

Vomiting.

May cause severe internal injury.

Small amounts may cause serious damage.

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4.3 Indication of any immediate medical attention and special treatment needed

In case of ingestion or affecting of eyes, seek medical help immediately. For special medical advice, contact the Toxicology Information Centre.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents:

The product itself is not flammable.

Alcohol resistant foam, carbon dioxide (CO₂), water spray or water mist, extinguishing powder.

Use fire extinguishing methods suitable to surrounding conditions.

For safety reasons unsuitable extinguishing agents: Water with full jet.

5.2 Special hazards arising from the substance or mixture

Formation of irritating, toxic and harmful fumes of burning is possible in case of fire.

Possibly they may be released:

Highly toxic and corrosive gases or vapours.

Inhalation of hazardous decomposition products of burning may result in damaged health.

5.3 Advice for firefighters

Protective equipment:

Do not inhale explosion gases or combustion gases.

According to size of fire.

Corresponding protective insulation breathing apparatus and overpressure counter-chemical protective clothing.

5.4 Further information

Cool with water the products in enclosed packaging, which is near the fire.

If possible, remove the products in un-damaged packaging from the danger area.

Store the contaminated extinguishing water separately and do not let it into the sewerage.

Remove the extinguishing water or used extinguishing materials together with the remnants of the fire according to the corresponding regulations.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Respect the instructions set forth in Sections 7 and 8 of the safety data sheet.

For non-emergency personnel:

In case of spillage or accidental release, wear personal protective equipment as specified in section 8 to prevent contamination.

Leave the danger zone, if possible, use existing emergency plans if necessary.

Ensure adequate ventilation.

Use personal protective equipment.

Avoid contact with eyes and skin.

Prevent the possibility of slipping on the spilled product.

Prevent entry of unauthorized and unprotected persons.

For emergency responders:

See section 8 for suitable protective equipment and material specification

6.2 Environmental precautions

The product is classified as dangerous for the environment.

Do not allow to enter sewers/surface or ground water.

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MATERIAL SAFETY DATA SHEET

epicGEN Hybridization Buffer

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and place into suitable and marked vessels.

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.

Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

In addition to the information provided in this section, important information is also provided in Sections 6 and 8.

Information about fire - and explosion protection:

No special measures required.

Respect general regulations on fire prevention.

Handling:

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.

Ensure good ventilation.

Prevent formation of aerosols.

Use personal protective equipment.

Avoid contact with eyes and skin.

Avoid long-term or intense skin contact.

Use working methods according to operating instructions.

Observe directions on label and instructions for use.

General hygiene measures for the handing of chemicals are applicable.

Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.

Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

Do not eat, drink, smoke, or snuff during use.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Secure impermeable floors against the liquids.

Store only in unopened original receptacles.

Vessels already open must be reclosed carefully and stored in the upright position in order to prevent leakage of the contents.

Information about storage in one common storage facility:

Keep away from food, drink and animal feedings tuffs.

Further information about storage conditions:

Store in a well-ventilated place.

Store in a dry and cool place.

Keep containers tightly sealed.

Protect from exposure to the light.

Protect containers from physical damage.

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Store under lock and key and with access restricted to technical experts or their assistants only. Keep out of reach of children.

7.3 Specific end use(s)

The product is intended only for professional use.

Specific use is stated in the manual for use on the product packaging label or in the product documentation.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs: No values available. **PNECs:** No values available.

Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with biological limit values.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under WEL or IOEL values, suitable breathing protection should be worm. Applies only if maximum permissible exposure values are listed here.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat, drink, smoke or sniff while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Do not inhale gases/fumes/aerosols.

Avoid contact with the eyes and skin.

8.2.2 Personal protective equipment

a) Eye/face protection:



Not required during regular use.

Alternatively, use closed safety glasses (EN 166).

b) Skin protection



Body protection

As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.

When handling laboratory scale quantities, a lab coat is recommended.

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Hand protection

Protective gloves (EN ISO 374-1).

Selection of the glove material on consideration of the penetration times rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Preventive skin protection by use of skin-protecting agents is recommended.

Material of gloves:

Not determined.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:

Not determined.

No tests have been performed, glove resistance must be tested before use.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection:



Unnecessary during regular use.

In case of insufficient ventilation use a suitable breathing mask with a filter (EN 14387+A1).

Not classified as a flammability hazard.

Observe wearing time limitations for respiratory protection equipment.

Recommended filter device for short term use:

Not determined.

Thermal hazards:

Not applicable.

Environmental exposure controls

Adhere to usual measures for environmental protection, see Section 6.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties 9.1

General Information

Flammability:

Physical state: Liquid. Colour: Colourless. Odour: Odourless. Melting point/freezing point: Not determined. Boiling point or initial boiling point and boiling range: Not determined.

Lower and upper explosion limit Lower: Not determined. Upper: Not determined.

Flash point: Not applicable. Auto-ignition temperature: Not determined.

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Decomposition temperature: Not determined. pH: Not determined.

Viscosity

Kinematic viscosity:

Dynamic viscosity:

Solubility in water:

Partition coefficient n-octanol/water (log value):

Vapour pressure:

Not determined.

Not determined.

Not determined.

Not determined.

Density and/or relative density

Density:
Relative density:
Vapour density:
Not determined.
Not determined.
Not determined.
Not determined.
Not determined.
Not determined.

9.2 Other information

Important information on protection of health and environment, and on safety.

Ignition temperature: Not determined.

Explosive properties: Product does not present an explosion

hazard.

Solvent content

VOC (2010/75/EC):

Oxidising properties:

Evaporation rate:

Relative evaporation rate:

Not determined.

Not determined.

Not determined.

Information with regard to physical hazard classes

Void. **Explosives:** Flammable gases: Void. Aerosols: Void. Oxidising gases: Void. Gases under pressure: Void. Flammable liquids: Void. Flammable solids: Void. Self-reactive substances and mixtures: Void. Pyrophoric liquids: Void. Pyrophoric solids: Void. Self-heating substances and mixtures: Void. Substances and mixtures, which emit flammable gases in contact with water: Void. Oxidising liquids: Void. Void. Oxidising solids: Organic peroxides: Void. Corrosive to metals: Void. Desensitised explosives: Void.

9.3 Additional information:

No relevant information available.

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

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10.2 Chemical stability

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.3 Possibility of hazardous reactions

No dangerous reactions known

10.4 Conditions to avoid

Protect against high temperatures. Protect against direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

Poisonous gases/vapours

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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

Acute toxicity: Fatal if swallowed.

Relevant toxicological values for classification:			
Oral	ATE	ATE 18.66 mg/kg	
Dermal	ATE	2,003.73 mg/kg	
75-57-0 tetramethylammonium chloride			
Oral	LD50	D50 47 mg/kg (rat) (OECD 401 - Acute Oral Toxicity)	
Dermal	LD50 > 200–500 mg/kg (rabbit) (OECD 402 - Acute Dermal Toxicity)		

Primary irritant effect

Skin corrosion/irritation:

Causes skin irritation.

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.

STOT-single exposure:

Causes damage to the central nervous system. Route of exposure: Oral.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

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Additional toxicological information:

No relevant information is available.

Acute effects:

Skin irritation – Skin Irrit. category 2. Acute oral toxicity, Hazard category 2.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

No CMR effects are known.

11.2 Additional Information

Endocrine disrupting properties:

None of the ingredients is listed.

Other information: No other relevant information available on adverse effects on health.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

Hazardous to the aquatic environment – Aquatic Chronic 2.

75-57-0 tetramethylammonium chloride		
LC50/96 h	462 mg/l (fish) (OECD 203 - Fish, Acute Toxicity Test) Pimephales promelas	
NOEC/11 d	0.03 mg/l (daphnia) Daphnia magna	

12.2 Persistence and degradability

No further relevant information available.

Behaviour in waste water treatment plants:

No relevant information is available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

The product does not contain substances classified as PBT or vPvB and included in the list of substances subject to authorization (Annex XIV of EP and R Regulation No 1907/2006, as amended).

PBT: No relevant information is available.

vPvB: No relevant information is available.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Remark: Toxic for fish.

Additional ecological information

AOX-indication: No relevant information is available.

General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water. Do not allow product to reach ground water, water course or sewage system, even in small

guantities

Danger to drinking water if even extremely small quantities leak into the ground.

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Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Recommendation:

Must not be disposed together with household waste. Do not allow product to reach sewage system.

Remove product residues according to the corresponding local directives in the adequate equipment as hazardous waste. E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

Waste disposal key:

The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances (2001/118/EC, 2001/119/EC, 2001/573/EC, 2014/955/EU).

European waste catalogue and hazardous properties of waste:		
18 01 06*	chemicals consisting of or containing hazardous substances	
15 01 10*	packaging containing residues of or contaminated by hazardous substances	
15 01 02	plastic packaging	
HP4	Irritant - skin irritation and eye damage	
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity	
HP6	Acute Toxicity	
HP14	Ecotoxic	

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be reused.

Non contaminated packagings may be recycled.

Dispose of packaging that cannot be cleaned in the same manner as the mixture.

Empty container completely.

Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Hand over possible empty packaging to an authorised organisation, which is entitled to their disposal.

Recommended cleansing agents:

Water, if necessary, together with cleansing agents.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council. Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

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SECTION 14 TRANSPORT INFORMATION

14.1 UN number

ADR, IMDG, IATA UN2810

14.2 UN proper shipping name

ADR 2810 TOXIC LIQUID, ORGANIC, N.O.S. (tetramethylammonium chloride),

ENVIRONMENTALLY HAZARDOUS

IMDG TOXIC LIQUID, ORGANIC, N.O.S. (tetramethylammonium chloride), MARINE

POLLUTANT

IATA TOXIC LIQUID, ORGANIC, N.O.S. (tetramethylammonium chloride)

14.3 Transport hazard class(es)

ADR/RID:



Class: 6.1 (T1) Toxic substances

Label: 6.1

IMDG:



Class: 6.1 (T1) Toxic substances

Label: 6.1

IATA:



Class: 6.1 (T1) Toxic substances

Label: 6.1

14.4 Packaging group

ADR/RID, IMDG, IATA: III

14.5 Environmental hazards

Product contains environmentally hazardous substances: tetramethylammonium chloride

Marine pollutant: Symbol (fish and tree)

Special marketing (ADR): Symbol (fish and tree)

14.6 Special precautions for user

Warning: Toxic substances

Hazard identification number (Kemler code): 60
EMS Number: F-A, S-A

Stowage Category:

Stowage Code: SW2 Clear of living quarters

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

Transport/Additional information: Danger code and packing code on request.

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ADR

Limited quantities (LQ): 5L Excepted quantities (EQ): Code: E1

> Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml

Transport category: 2
Tunnel restriction code: E

IMDG

Limited quantities (LQ): 5L Excepted quantities (EQ): Code: E1

Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml UN 2 8 1 0 TOXIC LIQUI D, ORGANIC, N. O. S. (TETRAMETHYLAMMONIUM CHLORIDE), 6.1, 111,

ENVIRONMENTALLY HAZARDOUS

SECTION 15 REGULATORY INFORMATION

UN "Model Regulation":

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

Directive 2004/42/EC of the European Parliament and the Council: Does not apply.

Named dangerous substances - ANNEX I: None of the ingredients is listed.

Seveso category:

H2 ACUTE TOXIC

E2 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) for the application of lower-tier requirements: 50 t Qualifying quantity (tonnes) for the application of upper-tier requirements: 200 t REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II: None of the ingredients is listed.

REGULATION (EU) 2019/1148:

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors:

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors:

None of the ingredients is listed.

Legal regulations of the European Community:

Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), applicable as from 1 January 2025.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 of 16 December 2008 on classification, labelling and packaging of substances and mixtures,

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amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, as amended.

COMMISSION REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: 2016/918 (8. ATP from 1.2.2018), 2016/1179 (9. ATP from 1.3.2018), 2017/776 (10. ATP from 1.12.2018), 2018/669 (11. ATP from 1.12.2019), 2019/521 (12. ATP from 17.10.2020), 2018/1480 (13. ATP from 1.5.2020). COMMISSION DELEGATED REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures:

2020/217 (14. ATP from 1.10.2021), 2020/1182 (15. ATP from 1.3.2022), 2021/643 (16. ATP from 10.5.2021), 2021/849 (17. ATP from 17.12.2022), 2022/692 (18. ATP from 1.12.2023), 2023/1434 (19. ATP from 1.8.2023), 2023/1435 (20. ATP from 1.2.2025).

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Warning:

The safety data sheet contains data needed for securing safety and health protection during work and environ-mental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

Relevant phrases:

H300 Fatal if swallowed.
H311 Toxic in contact with skin.
H315 Causes skin irritation.
H370 Causes damage to organs.

H411 Toxic to aquatic life with long lasting effects.

Training hints:

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other ex-pert documents for the product, issued by the supplier.

Recommended restriction of use:

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about

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the work procedures, hazardous properties of the product, and also about the necessary safety measures.

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to ad-here to the product usage conditions and to respect the safety instructions for health and environmental protection.

Further information:

This product must be stored, sold, and used in accordance with valid hygienic regulations.

Classification according to Regulation (EC) No 1272/2008:		
Acute toxicity – oral Skin corrosion/irritation Specific target organ toxicity (single exposure) Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	Calculation method	

First issue of SDS: 05.11.2025

Documents used to prepare SDS:

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par

route (European Agreement Concerning the International Carriage of

Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, ioaccumulative and Toxic SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity – Category 2 Acute Tox. 3: Acute toxicity – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard –

Category 2

Information on data sources used in compiling the safety data sheet:

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2020/878 of 18 June 2020.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

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SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: epicGEN Hybridization Buffer Enhancer

UFI: Not apply.

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

For research and development purposes only. No specific uses advised against are identified. Details of the supplier of the safety data sheet BioVendor – Laboratorní medicína a.s.

Karásek 1767/1 621 00 Brno Czech Republic

Identification number: 63471507

Tel: +420 549 124 185 E-mail: <u>info@biovendor.com</u> Web: <u>www.biovendor.com</u>

1.3 Emergency telephone number

European Chemicals Agency. National helpdesks contact details:

https://echa.europa.eu/support/helpdesks

Links to Poison Centers and Clinical Toxicologists all over the World:

https://www.eapcct.org/index.php?page=links

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Carc. 2 H351 Suspected of causing cancer.
Repr. 1B H360D May damage the unborn child.

STOT RE 2 H373 May cause damage to organs (Blood) through prolonged or repeated

exposure if swallowed.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Hazard pictogram:



GHS08

Signal word: Danger

Hazard-determining components of labelling: formamide

Hazard statements:

H351 Suspected of causing cancer. H360D May damage the unborn child.

H373 May cause damage to organs (Blood) through prolonged or repeated exposure if

swallowed

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MATERIAL SAFETY DATA SHEET

epicGEN Hybridization Buffer Enhancer

Precautionary statements:

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapours.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P405 Store locked up.

P501 Dispose of contents/ container to an approved waste disposal plant.

Additional information: Void. Reduced Labelling (≤ 125 ml)

Hazard pictogram:



GHS08

Signal word: Danger **Hazard statements:**

H351 Suspected of causing cancer. H360D May damage the unborn child.

Precautionary statements:

P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P405 Store locked up.

P501 Dispose of contents/ container to an approved waste disposal plant.

Additional information: The product is intended for professional use only and this corresponds to its labelling on the packaging.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

vPvB:

The mixture does not contain substances classified at the date of preparation of the safety data sheet as PBT according to Regulation (EC) No 1907/2006 (REACH) in a concentration equal to or greater than 0.1 % by weight.

Determination of endocrine-disrupting properties

The mixture does not contain substances that have been identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

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SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Component	Classification	Concentration
CAS: 75-12-7	formamide	≤ 100%
EINECS: 200-842-0	Carc.2 - H351	
REACH: 01-2119496064-35-XXXX	Repr. 1B - H360	
	STOT RE 2 – H373	

SVHC: Formamide is included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

Additional information:

For the wording of the listed hazard phrases refer to section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information:

Get medical attention if any discomfort continues. Show this Safety Data Sheet to the medical personnel.

Inhalation:

Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Loosen tight clothing such as collar, tie or belt.

Get medical attention if symptoms are severe or persist.

Skin contact:

Take off immediately all contaminated clothing.

Rinse skin with water/ shower.

Eye contact:

Remove any contact lenses and open eyelids wide apart.

Rinse with plenty of water.

Get medical attention if any discomfort continues.

Ingestion:

Rinse mouth thoroughly with water.

Get medical advice/attention if you feel unwell.

Do not induce vomiting unless under the direction of medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

General information:

The severity of the symptoms described will vary dependent on the concentration and the length of exposure.

Inhalation:

Prolonged or repeated exposure may cause the following adverse effects:

Suspected of causing cancer.

Ingestion:

Prolonged or repeated exposure may cause the following adverse effects:

Suspected of causing cancer.

Skin contact:

Prolonged or repeated exposure may cause the following adverse effects:

Suspected of causing cancer.

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Eye contact:

No specific symptoms known. May be slightly irritating to eyes.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

The product is not flammable.

Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.

Use fire-extinguishing media suitable for the surrounding fire.

Unsuitable extinguishing media:

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Specific hazards:

Containers can burst violently or explode when heated, due to excessive pressure build-up.

Hazardous combustion products:

Thermal decomposition or combustion products may include the following substances: Harmful gases or vapours.

5.3 Advice for firefighters

Protective actions during firefighting:

Avoid breathing fire gases or vapours.

Evacuate area.

Keep upwind to avoid inhalation of gases, vapours, fumes and smoke.

Ventilate closed spaces before entering them.

Cool containers exposed to heat with water spray and remove them from the fire area if it can be done without risk.

Cool containers exposed to flames with water until well after the fire is out.

If a leak or spill has not ignited, use water spray to disperse vapours and protect men stopping the leak.

Control run-off water by containing and keeping it out of sewers and watercourses.

If risk of water pollution occurs, notify appropriate authorities.

5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Wear protective clothing as described in Section 8 of this safety data sheet.

No action shall be taken without appropriate training or involving any personal risk.

Do not touch or walk into spilled material.

6.2 Environmental precautions

Avoid discharge into drains or watercourses or onto the ground. Avoid discharge to the aquatic environment.

6.3 Methods and material for containment and cleaning up

Wear protective clothing as described in Section 8 of this safety data sheet.

Clear up spills immediately and dispose of waste safely.

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Small Spillages: Collect spillage.

Large Spillages: Absorb spillage with noncombustible, absorbent material. The contaminated absorbent may pose the same hazard as the spilled material. Collect and place in suitable waste disposal containers and seal securely. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage.

For waste disposal, see Section 13.

6.4 Reference to other sections

For information on safe handling, see Section 7.

For information on personal protective equipment, see Section 8.

For further information on health hazards, see Section 11.

For further information on environmental hazards, see Section 12.

For disposal information, see Section 13.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Read and follow manufacturer's recommendations.

Wear protective clothing as described in Section 8 of this safety data sheet.

Keep away from food, drink and animal feeding stuffs.

Handle all packages and containers carefully to minimise spills.

Keep container tightly sealed when not in use.

Avoid the formation of mists.

Suspected of causing cancer.

May damage the unborn child.

Pregnant or breastfeeding women should not work with this product if there is any risk of exposure.

Do not handle until all safety precautions have been read and understood.

Do not handle broken packages without protective equipment.

Do not reuse empty containers.

Wash promptly if skin becomes contaminated.

Take off contaminated clothing.

Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Store away from incompatible materials (see Section 10).

Store locked up.

Keep only in the original container. Keep container tightly closed, in a cool, well-ventilated place. Keep containers upright. Protect containers from damage.

Storage class (TRGS 510): 6.1C: Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects.

7.3 Specific end use(s)

The product is intended for professional use only.

Specific uses are listed in the instructions for use on the product label or in the product documentation.

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8.1 Control parameters

Ingredients with workplace control parameters:

DNELs:		
75-12-7 formamide		
Inhalative	DNEL - Long term exposure (8-hour TWA)	20 ppm; 37 mg/m ³
Inhalative	DNEL - Short term exposure (15-minute)	30 ppm; 56 mg/m ³

8.2 Exposure controls

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under Workplace Exposure Limit (WEL) or Indicative Occupational Exposure Limit (IOEL) values, suitable breathing protection should be worm. Applies only if maximum permissible exposure values are listed here.

8.2.1 Personal protective equipment

a) Eye/face protection:



Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses (EN 166).

b) Skin protection



Body protection

As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.

When handling laboratory scale quantities, a lab coat is recommended.



Hand protection

Protective gloves (EN ISO 374-1).

The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material.

Considering the data specified by the glove manufacturer, check during use that the gloves are retaining their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended.

c) Respiratory protection:



Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges should comply with European Standard EN14387. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136.

Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.

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d) Thermal hazards:

Not applicable.

e) Hygiene measures:

Wash after use and before eating, smoking and using the toilet. Do not eat, drink or smoke when using this product.

8.3 Environmental exposure controls:

Adhere to usual measures for environmental protection, see Section 6.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

General Information

Physical state: Viscous liquid.

Colour: Colourless to pale yellow.

Odour: Ammonia.

Melting point/freezing point: 2–3 °C

Boiling point or initial boiling point and boiling range: 210 °C

Flammability: Not classified as a flammability

hazard.

Lower and upper explosion limit

Lower: 2.7 % (V)
Upper: 19 % (V)
Flash point: 152 °C

Auto-ignition temperature:

Decomposition temperature:

PH:

Not determined.

Not determined.

4-10 at 200 g/l at 20 °C

. Viscosity

Kinematic viscosity:

Dynamic viscosity:

Solubility in water:

Partition coefficient n-octanol/water (log value):

Vapour pressure:

Not determined.

Not determined.

Not determined.

0.08 hPa at 20 °C

Density and/or relative density

Density: 1.134 g/cm3 at 25 °C Relative density: Not determined. Vapour density: Not determined. Relative gas density: Not determined.

9.2 Other information

Important information on protection of health and environment, and on safety.

Ignition temperature: Not determined.

Explosive properties: Product does not present an

explosion hazard.

Solvent content VOC (2010/75/EC):

Oxidising properties:

Evaporation rate:

Not determined.

Not determined.

Relative evaporation rate:

Not determined.

Information with regard to physical hazard classes

Explosives: Void.
Flammable gases: Void.
Aerosols: Void.
Oxidising gases: Void.
Gases under pressure: Void.
Flammable liquids: Void.

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Flammable solids:	Void.
Self-reactive substances and mixtures:	Void.
Pyrophoric liquids:	Void.
Pyrophoric solids:	Void.
Self-heating substances and mixtures:	Void.

Substances and mixtures, which emit flammable gases

in contact with water:

Oxidising liquids:

Oxidising solids:

Organic peroxides:

Corrosive to metals:

Desensitised explosives:

Void.

Void.

Void.

Void.

Void.

Void.

Void.

9.3 Other information

Dissociation constant: -0.48 at 20 °C

Relative vapor density: 1.56

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.2 Chemical stability

Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).

10.3 Possibility of hazardous reactions

Exothermic reaction with: Oxidizing agents bases

Risk of explosion with: Furfuryl alcohol, oxides of phosphorus, hydrogen peroxide, iodine, pyridine and sulfur trioxide

A risk of explosion and/or of toxic gas formation exists with the following substances: Water separating agents

Possible formation of: Hydrogen cyanide (hydrocyanic acid)

10.4 Conditions to avoid

Heat, strong heating.

10.5 Incompatible materials

No specific material or group of materials is likely to react with the product to produce a hazardous situation.

10.6 Hazardous decomposition products

Does not decompose when used and stored as recommended.

Thermal decomposition or combustion products may include the following substances: Harmful gases or vapours.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral – Rat – (male and female): 5325 mg/kg (OECD Test Guideline 401) LC50 Inhalation – Rat (male): 4 h – > 21 mg/l – vapor (OECD Test Guideline 403)

LD50 Dermal - Rat (male and female): > 3000 mg/kg

Remarks: (ECHA)

Skin corrosion/irritation

Skin - Rabbit result: No skin irritation - 20 h

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Remarks: (ECHA)

Serious eye damage/eye irritation

Eyes – Rabbit: slight irritation (OECD Test Guideline 405)

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Test Type: Ames test;

Test system: Escherichia coli/Salmonella typhimurium Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Test Type: in vitro test Test system: Other cell types

Metabolic activation: without metabolic activation Method: Regulation (EC) No. 440/2008, Annex, B.21

Result: positive

Test Type: in vitro test Test system: Embryo

Metabolic activation: without metabolic activation

Result: negative Remarks: (ECHA)

Test Type: In vivo micronucleus test

Species: Mouse

Cell type: Red blood cells (erythrocytes)

Application Route: Oral

Method: OECD Test Guideline 474

Result: negative

Test Type: In vivo micronucleus test

Species: Mouse

Cell type: Bone marrow

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Test Type: Genotoxicity in vivo Species: Drosophila melanogaster

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 477

Result: negative

Test Type: dominant lethal test

Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 478

Result: negative Carcinogenicity

Suspected of causing cancer.

Reproductive toxicity

May damage the unborn child.

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

Oral – May cause damage to organs through prolonged or repeated exposure.

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Aspiration hazard

No data available

11.2 Additional Information

Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information:

Repeated dose toxicity - Rat (male and female) - Oral - 90 d - NOAEL - 40-80 mg/kg

Remarks: Subchronic toxicity

Repeated dose toxicity - Rat (male) - Inhalation - 14 d

Repeated dose toxicity - Rat (male and female) - Dermal - 90 d - NOAEL - 100 mg/kg

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

Possible effect after contact with substance: Ataxia (impaired locomotor coordination)

Absorption may result in damage of the following: Liver, kidney

Other dangerous properties can not be excluded.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Species	Type of test	Exposure time	Value	Source
Fish (Leuciscus idus)	static test LC50	96 h	6.569 mg/l	ECHA
Aquatic invertebrates (Daphnia magna)	static test EC50	48 h	> 500 mg/l	ECHA
Algae (Desmodesmus subspicatus)	static test ErC50	96 h	> 500 mg/l	ECHA
Bacteria (activated sludge)	static test EC50	30 min	> 1000 mg/l	ECHA

12.2 Persistence and degradability

Biodegradability: aerobic – Exposure time 28 d

Result: 99 % – Readily biodegradable.

(OECD Test Guideline 301A)

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

When discharged properly, no impairments in the function of adapted biological wastewater treatment plants are to be expected.

Discharge into the environment must be avoided.

Additional ecological information

AOX-indication: Product does not contain any organic halogens.

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SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Recommendation:

Must not be disposed together with household waste. Do not allow product to reach sewage system.

Remove product residues according to the corresponding local directives in the adequate equipment as hazardous waste. E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

Waste disposal key:

The catalogue numbers with the asterisk (*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances (2001/118/EC, 2001/119/EC, 2001/573/EC, 2014/955/EU).

European waste catalogue and hazardous properties of waste:		
18 01 06*	chemicals consisting of or containing hazardous substances	
15 01 10*	packaging containing residues of or contaminated by hazardous substances	
15 01 02	plastic packaging	
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity	
HP7	Carcinogenity	
HP10	Toxic for reproduction	

Uncleaned packaging

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings may be reused.

Non contaminated packagings may be recycled.

Dispose of packaging that cannot be cleaned in the same manner as the mixture.

Empty container completely.

Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment. Put other waste away according to the material type into collection vessels for sorted waste.

Hand over possible empty packaging to an authorised organisation, which is entitled to their disposal.

Regulations:

Commission Decision No 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council. Commission Regulation (EU) No 1357/2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number

ADR/RID, IMDG, IATA: Void.

14.2 UN proper shipping name

ADR/RID, IMDG, IATA: Not dangerous goods

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14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA: Void.

14.4 Packaging group

ADR/RID, IMDG, IATA: Void.

14.5 Environmental hazards

ADR/RID: NO IMDG: NO IATA: NO

14.6 Special precautions for user

No data available.

SECTION 15 REGULATORY INFORMATION

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

Directive 2004/42/EC of the European Parliament and the Council: Does not apply.

Named dangerous substances – ANNEX I: None of the ingredients is listed.

REGULATION (EC) No 1907/2006 ANNEX XVII: Conditions of restriction for the group No 3.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II:

None of the ingredients is listed.

REGULATION (EU) 2019/1148:

Annex I – RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors:

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors:

None of the ingredients is listed.

Legal regulations of the European Community:

Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), applicable as from 1 January 2025.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major—accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, as amended.

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COMMISSION REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: 2016/918 (8. ATP from 1.2.2018), 2016/1179 (9. ATP from 1.3.2018), 2017/776 (10. ATP from 1.12.2018), 2018/669 (11. ATP from 1.12.2019), 2019/521 (12. ATP from 17.10.2020), 2018/1480 (13. ATP from 1.5.2020). COMMISSION DELEGATED REGULATION (EU) amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: 2020/217 (14. ATP from 1.10.2021), 2020/1182 (15. ATP from 1.3.2022), 2021/643 (16. ATP from 1.5.2021), 2021/849 (17. ATP from 17.12.2022), 2022/692 (18. ATP from 1.12.2023), 2023/1434 (19. ATP from 1.8.2023), 2023/1435 (20. ATP from 1.2.2025).

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out.

SECTION 16 OTHER INFORMATION

Warning:

The safety data sheet contains data needed for securing safety and health protection during work and environ-mental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

Relevant phrases:

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H373 Suspected of causing cancer.

Training hints:

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other ex-pert documents for the product, issued by the supplier.

Recommended restriction of use:

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about the work procedures, hazardous properties of the product, and also about the necessary safety measures.

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to ad-here to the product usage conditions and to respect the safety instructions for health and environmental protection.

Further information: This product must be stored, sold, and used in accordance with valid hygienic regulations.

First issue of SDS: 05.11.2025 Documents used to prepare SDS:

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

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Abbreviations and acronyms used in safety data sheet:

ADR: Accord relatif au transport international des marchandises dangereuses par route

(European Agreement Concerning the International Carriage of Dangerous

Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

SDS: Safety Data Sheet

SVHC: Substances of Very High Concern

TWA: Time weighted average

vPvB: very Persistent and very Bioaccumulative

Carc.2 Carcinogenicity, Category 2
Repr. 1B Reproductive toxicity, Category 1B

STOT RE 2: Specific Target Organ Toxicity – Repeated Exposure, Category 2

Information on data sources used in compiling the safety data sheet:

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency – head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No 2020/878 of 18 June 2020.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

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