

Safety Data Sheet

according to Regulation (EC) No 1907/2006

SARS-CoV-2 Kit with PULB

Revision date: 05.08.2020

Product code: 10096

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

SARS-CoV-2 Kit with PULB

Further trade names

This SDS covers the following products:

-PULB – PCR-compatible lysis buffer, Product code: 10097

-Master Mix, Product code 10098

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

Use as laboratory reagent.

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name: Curetis GmbH

Street: Max-Eyth-Str. 42

Place: D 71088 Holzgerlingen

Telephone: +49-(0)7031 –49195-55

Responsible Department: Dr. Gans-Eichler

Chemieberatung GmbH

Otto-Hahn-Str. 36

D-48161 Münster

Telefax: +49-(0)7031 - 4919519

e-mail: info@tge-consult.de

Tel.: +49(0)2534 6441185

www.tge-consult.de

1.4. Emergency telephone number:

Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful to aquatic life with long lasting effects.

2.2. Label elements**Regulation (EC) No. 1272/2008****Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

P273 Avoid release to the environment.

Additional advice on labelling

This labelling / classification refers to the product:

PULB – PCR-compatible lysis buffer: H412

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
	Master Mix:			%
56-81-5	Glycerol			15- 35 %
	200-289-5		01-2119471987-18	
	PULB – PCR-compatible lysis buffer:			%
9002-93-1	alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-Poly(oxy-1,2-ethanediyl)			0.3 - < 0.5 %
	Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H302 H315 H318 H400 H410			

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

Specific concentration limits and M-factors

CAS No	EC No	Chemical name	Quantity
		Specific concentration limits and M-factors	
9002-93-1		alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-Poly(oxy-1,2-ethanediyl)	0,3 - < 0,5 %
		M akut; H400: M=10	

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

No information available.

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

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Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**Carbon dioxide (CO₂). Dry extinguishing powder. alcohol resistant foam. Atomized water.**Unsuitable extinguishing media**

High power water jet.

5.2. Special hazards arising from the substance or mixtureCan be released in case of fire: Carbon monoxide. Carbon dioxide (CO₂).**5.3. Advice for firefighters**

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Safe handling: see section 7

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Eliminate leaks immediately.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

Treat the recovered material as prescribed in the section on waste disposal .

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

Wear suitable protective clothing. See section 8.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Recommended storage temperature: 20°C

Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

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See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
56-81-5	Glycerol, mist	-	10		TWA (8 h)	WEL

DNEL/DMEL values

CAS No	Substance	DNEL type	Exposure route	Effect	Value
56-81-5	Glycerol				
		Worker DNEL, long-term	inhalation	local	56 mg/m ³
		Consumer DNEL, long-term	inhalation	local	33 mg/m ³
		Consumer DNEL, long-term	oral	systemic	229 mg/kg bw/day

PNEC values

CAS No	Substance	Environmental compartment	Value
56-81-5	Glycerol		
		Freshwater	0,885 mg/l
		Freshwater (intermittent releases)	8,85 mg/l
		Marine water	0,088 mg/l
		Freshwater sediment	3,3 mg/kg
		Marine sediment	0,33 mg/kg
		Secondary poisoning	0,141 mg/kg
		Micro-organisms in sewage treatment plants (STP)	1000 mg/l

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

Provide adequate ventilation.

Protective and hygiene measures

Always close containers tightly after the removal of product. When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). BS/EN 166

Hand protection

Wear suitable gloves.

Suitable material:

FKM (fluororubber). - Thickness of glove material: 0,4 mm

Breakthrough time >= 8 h

Butyl rubber. - Thickness of glove material: 0,5mm

Breakthrough time >= 8 h

CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm

Breakthrough time >= 8 h

NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm

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Breakthrough time \geq 8 h

PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm

Breakthrough time \geq 8 h

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab apron.

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Respiratory protection necessary at:

-Exceeding exposure limit values

-Insufficient ventilation. and aerosol or mist formation

Suitable respiratory protective equipment: particulates filter device (DIN EN 143). Type: P1-3

The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Environmental exposure controls

No special precautionary measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	not determined
Odour:	characteristic
pH-Value:	not determined

Changes in the physical state

Melting point:	~0 °C
Initial boiling point and boiling range:	~100 °C
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined
Sustaining combustion:	Not sustaining combustion

Explosive properties

none

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	not determined

Auto-ignition temperature

Gas: not determined

Decomposition temperature: not determined

Oxidizing properties

none

Vapour pressure: not determined

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Density:	not determined
Water solubility:	not determined
Solubility in other solvents	
not determined	
Partition coefficient:	not determined
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Flow time:	not determined
Vapour density:	not determined
Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined

9.2. Other information

Solid content:	not determined
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SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Refer to chapter 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO₂).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicokinetics, metabolism and distribution

No data available.

Acute toxicity

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
56-81-5	Glycerol				
	oral	LD50 mg/kg	12600	Rat.	
	dermal	LD50 mg/kg	>21900	Rat.	
	inhalation (4 h) vapour	LC50 mg/l	(>2,57)	Rat.	ECHA
9002-93-1	alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-Poly(oxy-1,2-ethanediyyl)				

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	oral	LD50 mg/kg	1800	Rat	RTECS	
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Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

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.

Specific effects in experiment on an animal

No data available.

SECTION 12: Ecological information
12.1. Toxicity

The product has not been tested.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
56-81-5	Glycerol					
	Acute fish toxicity	LC50 mg/l	54000	96 h	Oncorhynchus mykiss	ECHA Dossier
9002-93-1	alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-Poly(oxy-1,2-ethanediyl)					
	Acute fish toxicity	LC50	>10 mg/l	96 h	Lepomis macrochirus	US EPA
	Acute algae toxicity	ErC50 mg/l	124,3	72 h	Poteriochromonas malhamensis	US EPA
	Acute crustacea toxicity	EC50 mg/l	0,011	48 h	Daphnia magna	US EPA

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
56-81-5	Glycerol	-1,76
9002-93-1	alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-Poly(oxy-1,2-ethanediyl)	4,86

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.

Non-contaminated packages may be recycled.

According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

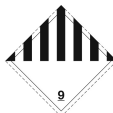
- 14.1. UN number:** UN 1845
- 14.2. UN proper shipping name:** Carbon dioxide, solid (Dry ice)
- 14.3. Transport hazard class(es):** 9
- 14.4. Packing group:** -
- Classification code: M11

Inland waterways transport (ADN)

- 14.1. UN number:** UN 1845
- 14.2. UN proper shipping name:** Carbon dioxide, solid (Dry ice)
- 14.3. Transport hazard class(es):** 9
- 14.4. Packing group:** N-S
- Classification code: M11

Marine transport (IMDG)

- 14.1. UN number:** UN 1845
- 14.2. UN proper shipping name:** CARBON DIOXIDE, SOLID (DRY ICE)
- 14.3. Transport hazard class(es):** 9
- 14.4. Packing group:** -
- Hazard label: 9



Special Provisions: -

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Limited quantity: 0
 Excepted quantity: E0
 EmS: F-C, S-V

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: UN 1845
14.2. UN proper shipping name: DRY ICE
14.3. Transport hazard class(es): 9
14.4. Packing group: -
 Hazard label: 9



Special Provisions: A48 A151 A805
 Limited quantity Passenger: Forbidden
 Passenger LQ: Forbidden
 Excepted quantity: E0
 IATA-packing instructions - Passenger: 954
 IATA-max. quantity - Passenger: 200 kg
 IATA-packing instructions - Cargo: 954
 IATA-max. quantity - Cargo: 200 kg

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Refer to section 6-8

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

not relevant

SECTION 15: Regulatory information

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

EU regulatory information

Authorisations (REACH, annex XIV):
 alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-Poly(oxy-1,2-ethanediyl)
 2010/75/EU (VOC): No information available.
 2004/42/EC (VOC): No information available.
 Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2019/957)
 PULB – PCR-compatible lysis buffer:
 The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].
 REACH 1907/2006 Appendix XVII, No (mixture): 3

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:
 Glycerol

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SECTION 16: Other information

Changes

Rev. 1.0; Initial release: 05.08.2020

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

CAS Chemical Abstracts Service

CLP: Classification, Labelling and Packaging of substances and mixtures

DNEL: Derived No Effect Level

d: day(s)

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

ECHA: European Chemicals Agency

EWC: European Waste Catalogue

IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

h: hour

LOAEL: Lowest observed adverse effect level

LOAEC: Lowest observed adverse effect concentration

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

NOAEL: No observed adverse effect level

NOAEC: No observed adverse effect concentration

NLP: No-Longer Polymers

N/A: not applicable

OECD: Organisation for Economic Co-operation and Development

PNEC: predicted no effect concentration

PBT: Persistent bioaccumulative toxic

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

REACH: Registration, Evaluation, Authorisation of Chemicals

SVHC: substance of very high concern

TRGS: Technische Regeln für Gefahrstoffe

UN: United Nations

VOC: Volatile Organic Compounds

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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Further Information

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:

Health hazards: Calculation method.

Environmental hazards: Calculation method.

Physical hazards: On basis of test data and / or calculated and / or estimated.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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