

Kit SDS Cover Sheet

PyroGene 192 Test Kit

Version 3.1

Revision Date 09.09.2019

Print Date 18.12.2020

Product Information

Product name : PyroGene 192 Test Kit

Material number : 50-658U

Components

rFC Substrate Vial	SDS attached
rFC Buffer	SDS attached
Endotoxin (E.coli) Low Conc in PEG/Lactose	SDS attached
Water LAL Reagent	SDS attached
Recombinant Factor C Enzyme Solution	SDS attached

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

rFC Substrate Vial

Version 3.1

Revision Date 09.09.2019

Print Date 18.12.2020

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

Product name : rFC Substrate Vial

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

Use of the Substance/Mixture : For Endotoxin Detection Use

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallengbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

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.

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

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**Suitable extinguishing media : Water spray
Dry powder
Foam**5.2 Special hazards arising from the substance or mixture**

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

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

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).

Dispose of in accordance with local regulations.

6.4 Reference to other sections

For personal protection see section 8.

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

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : No special precautions required.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Avoid splashes.

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Personal protective equipment

Eye protection	: Tightly fitting safety goggles
Hand protection	
Material	: Nitrile rubber
Rate of permeability	: > 480 min
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.
Respiratory protection	: No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: Aqueous solution
Colour	: no data available
Odour	: no data available
Odour Threshold	: no data available
pH	: no data available
Freezing point	: no data available
Boiling point/boiling range	: no data available
Flash point	: does not flash
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Vapour pressure	: no data available
Relative vapour density	: no data available
Relative density	: no data available
Density	: no data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: no data available

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Auto-ignition temperature : no data available

Decomposition temperature : no data available

Viscosity : no data available

Explosive properties : no data available

Oxidizing properties : no data available

9.2 Other information

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

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12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

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 Other adverse effects

Additional ecological information : no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
14.2 Proper shipping name : Not applicable
14.3 Transport hazard class : Not applicable
14.4 Packing group : Not applicable
14.5 Environmental hazards : no

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RID	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
DOT	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
TDG	:	Not dangerous goods
14.1 UN number	:	Not applicable
14.2 Proper shipping name	:	Not applicable
14.3 Transport hazard class	:	Not applicable
14.4 Packing group	:	Not applicable
14.5 Environmental hazards	:	no
14.6 Special precautions for user	:	none
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	:	Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

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Revision Date 09.09.2019

Print Date 18.12.2020

National regulatory information

Water contaminating class (Germany) : nwg not water endangering
Classification according to AwSV, Annex 1 (2.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Date format : dd.mm.yyyy

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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rFC Buffer

Version 3.1

Revision Date 09.09.2019

Print Date 18.12.2020

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

Product name : rFC Buffer

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

Use of the Substance/Mixture : For Endotoxin Detection Use

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallengbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

SAFETY DATA SHEET

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Dispose of in accordance with local regulations.

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : No special precautions required.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection : Safety glasses with side-shields

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Hand protection	
Material	: Nitrile rubber
Rate of permeability	: > 480 min
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.
Respiratory protection	: No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: Aqueous solution
Colour	: no data available
Odour	: no data available
Odour Threshold	: no data available
pH	: no data available
Freezing point	: no data available
Boiling point/boiling range	: no data available
Flash point	: does not flash
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Vapour pressure	: no data available
Relative vapour density	: no data available
Relative density	: no data available
Density	: no data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available

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Decomposition temperature : no data available

Viscosity : no data available

Explosive properties : no data available

Oxidizing properties : no data available

9.2 Other information

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

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Version 3.1

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12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

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 Other adverse effects

Additional ecological information : no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA

Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

IMDG

Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

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RID : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

TDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

14.6 Special precautions for user : none

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

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rFC Buffer

Version 3.1

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National regulatory information

Water contaminating class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR - Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC - European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN - European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS - Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV - Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide - National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG - Dutch Threshold Limit Value; TGV - Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA - Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Date format : dd.mm.yyyy

SAFETY DATA SHEET

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

Product name : Endotoxin (E.coli) Low Conc in PEG/Lactose

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

Use of the Substance/Mixture : For Endotoxin Detection Use

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

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.

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May form combustible dust concentrations in air.
Pyrogen

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

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of first aid measures**

If inhaled : Remove to fresh air.
If breathing is irregular or stopped, administer artificial respiration.
If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Call a physician immediately.

If swallowed : Clean mouth with water and drink afterwards plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Dry powder
Water spray
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

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Further information : Use water spray to cool unopened containers.

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

Personal precautions : Avoid dust formation.
Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.
Clean contaminated floors and objects thoroughly while observing environmental regulations.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : After cleaning, flush away traces with water.
Dispose of in accordance with local regulations.

6.4 Reference to other sections

For personal protection see section 8.

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

Advice on safe handling : Avoid formation of respirable particles.
Provide sufficient air exchange and/or exhaust in work rooms.
Avoid contact with skin and eyes.

Advice on protection against fire and explosion : Avoid dust formation. Take precautionary measures against static discharges.

Hygiene measures : Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep tightly closed in a dry and cool place.

Recommended storage temperature : 2 - 8 °C

7.3 Specific end use(s)

Specific use(s) : No information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Polyethylene glycol 8000	25322-68-3	TWA	1 000 mg/m ³	SMAK

Germany

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Polyethylene glycol 8000	25322-68-3	MAK (Inhalable fraction.)	1 000 mg/m ³	DFG MAK
Peak-limit: excursion factor (category)		Peak-limit: excursion factor (category) 8		
		(Inhalable fraction.)	1 000 mg/m ³	TRGS 900
Peak-limit: excursion factor (category)		Peak-limit: excursion factor (category) 8		

Denmark

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Polyethylene glycol 8000	25322-68-3	GV	1 000 mg/m ³	GV (DK)

8.2 Exposure controls

Engineering measures

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Eye protection : Safety glasses with side-shields

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.

Respiratory protection

: In the case of dust or aerosol formation use respirator with an approved filter.

Half mask with a particle filter P2 (EN 143)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: powder
Colour	: white
Odour	: odourless
Odour Threshold	: no data available
pH	: Not applicable
Melting point/range	: no data available
Boiling point/boiling range	: no data available
Flash point	: Not applicable
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Vapour pressure	: no data available
Relative vapour density	: no data available
Relative density	: no data available
Density	: no data available
Solubility(ies)	
Water solubility	: partly soluble
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Decomposition temperature	: no data available
Viscosity	: no data available
Explosive properties	: no data available
Oxidizing properties	: no data available

9.2 Other information

no data available

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SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : Keep away from heat and sources of ignition.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Further information**

Remarks: No data is available on the product itself.

The following toxicological data refer to:**Polyethylene glycol** (CAS-No.: 25322-68-3)**Acute toxicity**

Acute oral toxicity : LD50 (Rat): > 20 g/kg

Acute dermal toxicity : LD50 (Rabbit): > 20 g/kg

Skin corrosion/irritationSpecies: Rabbit
Result: Mild skin irritation**Serious eye damage/eye irritation**Species: Rabbit
Result: Mild eye irritation**Respiratory or skin sensitisation**Species: Guinea pig
Result: not sensitizing

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Germ cell mutagenicity

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Aspiration toxicity

No aspiration toxicity classification

Further information

Remarks: no data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

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 Other adverse effects

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

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TDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

14.6 Special precautions for user : none

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water contaminating class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Full text of other abbreviations

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ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Date format : dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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

Product name : Water LAL Reagent
EC-No. : 231-791-2

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

Use of the Substance/Mixture : Scientific research and development

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com
Responsible/issuing person

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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2.3 Other hazards

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.

SECTION 3: Composition/information on ingredients

3.1 Substances

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No hazards which require special first aid measures.

In case of skin contact : No hazards which require special first aid measures.

In case of eye contact : No hazards which require special first aid measures.

If swallowed : No hazards which require special first aid measures.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Not combustible.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

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

Personal precautions : Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).

6.4 Reference to other sections

For personal protection see section 8.

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

Advice on protection against fire and explosion : Stable under normal conditions.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep tightly closed in a dry and cool place. Do not freeze.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Eye protection : No special precautions required.

Hand protection

Remarks : Wear suitable gloves. Please observe the instructions

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	regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.
Skin and body protection	: Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.
Respiratory protection	: No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: Aqueous solution
Colour	: colourless
Odour	: odourless
Odour Threshold	: no data available
pH	: no data available
Melting point/range	: 0,1 °C
Boiling point/boiling range	: 100 °C
Flash point	: does not flash Other information: Does not sustain combustion.
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Vapour pressure	: 23 mbar (20 °C) 1 013 mbar (100 °C) 17,5 hPa (20 °C)
Relative vapour density	: no data available
Relative density	: 1
Density	: 1 g/cm ³ (4 °C)
Solubility(ies)	

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Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	no data available
Auto-ignition temperature	:	no data available
Decomposition temperature	:	no data available
Viscosity	:	no data available
Explosive properties	:	no data available
Oxidizing properties	:	no data available

9.2 Other information

Flammability (liquids)	:	Does not sustain combustion.
Molecular weight	:	18,01 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Stable under normal conditions.
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10.4 Conditions to avoid

Conditions to avoid	:	Not applicable
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10.5 Incompatible materials

Materials to avoid	:	none
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10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Germ cell mutagenicity

Genotoxicity in vitro	:	Test Type: Ames test Result: negative
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Further information

Remarks: No data is available on the product itself.

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SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish : Remarks: Not applicable

12.2 Persistence and degradability

Biodegradability : Remarks: Not applicable

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: Not applicable

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: Not applicable

12.5 Results of PBT and vPvB assessment

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 Other adverse effects

Additional ecological information : Not applicable

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : Marine pollutant: no

ADR : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

RID : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

DOT : Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

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Water LAL Reagent

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Revision Date 09.09.2019

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TDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

14.6 Special precautions for user : none

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water contaminating class (Germany) : nwg not water endangering

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE -

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Water LAL Reagent

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Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

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according to Regulation (EC) No. 1907/2006

Recombinant Factor C Enzyme Solution

Version 3.1

Revision Date 09.09.2019

Print Date 18.12.2020

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

Product name : Recombinant Factor C Enzyme Solution

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

Use of the Substance/Mixture : For Endotoxin Detection Use

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

Lonza Copenhagen ApS
Strandhaven 12
DK-2665 Vallensbaek Strand, Denmark
Business Telephone: + 45 4356 7400

E-mail address : sds@lonza.com

Responsible/issuing person

1.4 Emergency telephone numberEmergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

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

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Dry powder
Foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Use water spray to cool unopened containers.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

6.4 Reference to other sections

For personal protection see section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required.

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Countries not listed may have their own country specific values.

Occupational Exposure Limits

Belgium

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	BE/OEL

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Denmark

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	GV (Total dust.)	3 mg/m3	GV (DK)

France

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	VME	10 mg/m3	FVL

Italy

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	OEL (IT)

Spain

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	VLA

United Kingdom

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sucrose	57-50-1	TWA	10 mg/m3	EH40 WEL
		STEL	20 mg/m3	EH40 WEL

8.2 Exposure controls

Engineering measures

Avoid splashes.

Personal protective equipment

Eye protection : Tightly fitting safety goggles

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection

: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

Respiratory protection

: No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Aqueous solution

Colour : clear, yellow

Odour : no data available

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Odour Threshold	: no data available
pH	: 5,7 - 6,3
Freezing point	: no data available
Boiling point/boiling range	: no data available
Flash point	: does not flash
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Upper explosion limit	: no data available
Lower explosion limit	: no data available
Vapour pressure	: no data available
Relative vapour density	: no data available
Relative density	: no data available
Density	: no data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Decomposition temperature	: no data available
Viscosity	: no data available
Explosive properties	: no data available
Oxidizing properties	: no data available

9.2 Other information

no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal conditions.

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10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under normal conditions.

10.4 Conditions to avoid

Conditions to avoid : no data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored normally.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Further information

Remarks: No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: no data available

12.2 Persistence and degradability

Biodegradability : Result: no data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: no data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: no data available

12.5 Results of PBT and vPvB assessment

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 Other adverse effects

Additional ecological information : no data available

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

SECTION 14: Transport information

IATA Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

IMDG Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : Marine pollutant: no

ADR Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

RID Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

DOT : Not dangerous goods

- 14.1 UN number : Not applicable
- 14.2 Proper shipping name : Not applicable
- 14.3 Transport hazard class : Not applicable
- 14.4 Packing group : Not applicable
- 14.5 Environmental hazards : no

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TDG : Not dangerous goods

14.1 UN number : Not applicable

14.2 Proper shipping name : Not applicable

14.3 Transport hazard class : Not applicable

14.4 Packing group : Not applicable

14.5 Environmental hazards : no

14.6 Special precautions for user : none

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

National regulatory information

Water contaminating class (Germany) : WGK 2 obviously hazardous to water
Classification according to AwSV, Annex 1 (5.2)

15.2 Chemical safety assessment

not required

SECTION 16: Other information

Further information

Full text of other abbreviations

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