

Kit SDS Cover Sheet

Endotoxin Challenge Vials 25 vials/kit

Version 3.0

Revision Date 16.12.2021

Print Date 08.12.2024

Product Information

Product name : Endotoxin Challenge Vials 25 vials/kit

Material number : 00192568

Components

Lipopolysaccharides from Escherichia coli High Concentration

SDS attached

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according to Regulation (EC) No. 1907/2006

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

Product name : Lipopolysaccharides from Escherichia coli High Concentration
Substance name : Lipopolysaccharide

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

Use of the Substance/Mixture : Endotoxin Indicator for Depyrogenation

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.

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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.

Ecological information: 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.

Toxicological information: 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.

May form combustible dust concentrations in air.

Pyrogen

SECTION 3: Composition/information on ingredients**3.1 Substances**

Substance name : Lipopolysaccharide

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 off with soap and water.

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

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.

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4.3 Indication of any immediate medical attention and special treatment neededTreatment : 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 : 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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**Personal precautions : Use personal protective equipment.
Avoid dust formation.**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**

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- Advice on safe handling : Minimize dust generation and accumulation.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Advice on protection against fire and explosion : Avoid dust formation. During processing, dust may form explosive mixture in air.
- 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.

Recommended storage temperature : 2 - 8 °C

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 : Safety glasses with side-shields
- Hand protection
- Material : Nitrile rubber
- Rate of permeability : > 480 min
- Skin and body protection : No special protective equipment required.
- Respiratory protection : Respirator must be worn if exposed to dust.

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SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state	: solid
Appearance	: powder, (lyophilised)
Colour	: white
Odour	: odourless
Melting point/freezing point	: no data available
Initial boiling point and boiling range	: no data available
Flammability	: no data available
Upper explosion limit / upper flammability limit	: Not applicable
Lower explosion limit / Lower flammability limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature Decomposition temperature	: no data available
pH	: Not applicable
Viscosity Viscosity, kinematic	: Not applicable
Solubility(ies) Water solubility	: partly soluble
Partition coefficient: n-octanol/water	: no data available
Vapour pressure	: no data available
Relative density	: no data available
Density	: no data available
Relative vapour density	: Not applicable

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Particle characteristics : no data available

9.2 Other informationno 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 productsNo decomposition if stored normally.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute inhalation toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisationRemarks: no data available

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Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

11.2 Information on other hazards**Endocrine disrupting properties**

Assessment : 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.

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

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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 Endocrine disrupting properties

Endocrine disrupting potential : 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

Endocrine disrupting potential : 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.

Additional ecological information : no data available

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-CODE 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

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

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 (EU) 2019/1021 on persistent organic pollutants (recast) : 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 hazard class (Germany) : WGK 1 slightly hazardous to water
Remarks: Classification according to AwSV, Annex 1 (4)

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15.2 Chemical safety assessment

not required

SECTION 16: Other 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

Further information

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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