

Kit SDS Cover Sheet**PYROGENT BULK KIT 0.125 EU/ML SENSITIVE**

Version 3.0

Revision Date 16.12.2021

Print Date 14.12.2024

Product Information

Product name : PYROGENT BULK KIT 0.125 EU/ML SENSITIVE

Material number : F245U-125

Components

Pyrogent, 1.8 ml Vial 0.125 EU/ml

SDS attached

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Pyrogen, 1.8 ml Vial 0.125 EU/ml

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

Product name : Pyrogen, 1.8 ml Vial 0.125 EU/ml

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)**

Skin irritation, Category 2

H315: Causes skin irritation.

Eye irritation, Category 2

H319: Causes serious eye irritation.

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

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Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation.
Precautionary statements	:	<p>Prevention:</p> <p>P264 Wash skin thoroughly after handling. P280 Wear protective gloves/ eye protection/ face protection.</p> <p>Response:</p> <p>P302 + P352 IF ON SKIN: Wash with plenty of water. P332 + P313 If skin irritation occurs: Get medical advice/ attention. P337 + P313 If eye irritation persists: Get medical advice/ attention. P362 + P364 Take off contaminated clothing and wash it before reuse.</p>

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
Sodium hydroxide	1310-73-2	Met. Corr. 1; H290	>= 0,5 - < 1

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	215-185-5 011-002-00-6 01-2119457892-27-XX XX	Skin Corr. 1A; H314 Eye Dam. 1; H318	
		specific concentration limit Skin Irrit. 2; H315 0,5 - < 2 % Eye Irrit. 2; H319 0,5 - < 2 % Skin Corr. 1A; H314 >= 5 % Skin Corr. 1B; H314 2 - < 5 %	

For explanation of abbreviations see section 16.

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.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Consult a physician.
- 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 : Call a physician immediately.
Clean mouth with water and drink afterwards plenty of water.
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.

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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 : Chlorine
Magnesium oxides
Nitrogen oxides (NO_x)
Carbon oxides (CO_x)
Hydrogen chloride (HCl)

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 : Avoid dust formation.
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 : Provide sufficient air exchange and/or exhaust in work rooms.

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Avoid formation of respirable particles.
Avoid contact with skin and eyes.

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 : No special precautions required.

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

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

Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	STEL (Inhalable fraction.)	2 mg/m ³	SMAK
		TWA (Inhalable fraction.)	2 mg/m ³	SMAK

Denmark

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	LOFT	2 mg/m ³	GV (DK)

France

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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	VME	2 mg/m3	FVL

Italy

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	TLV-C	2 mg/m3	OEL (IT)

Spain

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	STEL	2 mg/m3	VLA

Sweden

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	TGV (Inhalable dust.)	2 mg/m3	SWO
		TWA (Inhalable dust.)	1 mg/m3	SWO

United Kingdom

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sodium hydroxide	1310-73-2	STEL	2 mg/m3	EH40 WEL

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium hydroxide	Workers	Inhalation	Long-term local effects	1 mg/m3
	Consumers	Inhalation	Long-term local effects	1 mg/m3
Calcium chloride dihydrate	Workers	Inhalation	Long-term local effects	5 mg/m3
	Consumers	Inhalation	Acute local effects	5 mg/m3
	Consumers	Inhalation	Long-term local effects	2,5 mg/m3
	Workers	Inhalation	Acute local effects	10 mg/m3

8.2 Exposure controls

Engineering measures

It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Use only appropriately classified electrical equipment and powered industrial trucks.

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	: In the case of dust or aerosol formation use respirator with an approved filter. Half mask with a particle filter P2 (EN 143)

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

Physical state	: solid
Appearance	: (lyophilised)
Colour	: no data available
Odour	: no data available
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

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Solubility(ies)	
Water solubility	: no data available
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
Particle characteristics	: 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 hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

Acute oral toxicity : Remarks: no data available

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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 sensitisation

Remarks: no data available

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

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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 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 contents/container in accordance with local regulation.
Contact waste disposal services.

Contaminated packaging : Dispose of as unused product.

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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 2 obviously hazardous to water
Remarks: Classification according to AwSV, Annex 1 (5.2)

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15.2 Chemical safety assessment

not required

SECTION 16: Other information**Classification of the mixture:**

Skin Irrit. 2 H315

Eye Irrit. 2 H319

Classification procedure:

Calculation method

Calculation method

Full text of H-Statements

H290 : May be corrosive to metals.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.

Full text of other abbreviations

Eye Dam. : Serious eye damage
Met. Corr. : Corrosive to metals
Skin Corr. : Skin corrosion

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

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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

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.

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