

Trade name: SYSMEX STERILIZER**Current version :** 4.0.1, issued: 04.05.2022**Replaced version:** 4.0.0, issued: 16.11.2020**Region:** GB**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name****SYSMEX STERILIZER****1.2 Relevant identified uses of the substance or mixture and uses advised against****Relevant identified uses of the substance or mixture**

For in-vitro diagnosis

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet**Address**

SYSMEX LTD

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MK8 8DF

Telephone no. +44 (0)333 320 3460

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Advice on Safety Data Sheet

info@sysmex-europe.com

1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

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

Aquatic Chronic 2; H411

Classification information

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:

Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP

Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)****Hazard pictograms**

GHS09

Signal word

-

Hazard statement(s)

H411

Toxic to aquatic life with long lasting effects.

Hazard statements (EU)

EUH208

Contains Poly(hexamethylenebiguanide) hydrochloride. May produce an allergic reaction.

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P273 Avoid release to the environment.
 P391 Collect spillage.
 P501 Dispose of contents/container to a facility in accordance with local and national regulations.

2.3 Other hazards

PBT assessment
 No data available.

vPvB assessment
 No data available.

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

Not applicable. The product is not a substance.

3.2 Mixtures**Hazardous ingredients**

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration
			%
1	Poly(hexamethylenebiguanide) hydrochloride		
	27083-27-8 - 616-207-00-X -	Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 Carc. 2; H351 Eye Dam. 1; H318 Skin Sens. 1B; H317 STOT RE 1; H372	< 0.50 wt%

Full Text for all H-phrases and EUH-phrases: pls. see section 16

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	-	-	M = 10	M = 10

No	Route, target organ, concrete effect
1	H372 inhalational; respiratory tract; -

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

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact

Wash off immediately with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Call a doctor immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray jet; Foam; Extinguishing powder

Unsuitable extinguishing media

High power water jet

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO₂); Carbon monoxide (CO); Nitrogen oxides (NO_x); chlorine compounds

5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing. Run-off water from fire fighting must not be discharged into drains or enter surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Avoid contact with skin, eyes and clothing.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil. In case of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When collected, handle material as described under the section heading "Disposal considerations".

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe the usual precautions for handling chemicals.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Avoid contact with eyes and skin.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

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

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

Incompatible products

None known

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

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No parameters available for monitoring.

8.2 Exposure controls**Appropriate engineering controls**

No data available.

Personal protective equipment**Respiratory protection**

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Eye / face protection

Safety glasses with side protection shield (EN 166)

Hand protection

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Other

Normal chemical work clothing.

Environmental exposure controls

No data available.

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

liquid

Form/Colour

liquid

clear

Odour

odourless

pH value

Comments

neutral

Boiling point / boiling range

No data available

Melting point/freezing point

No data available

Decomposition temperature

No data available

Flash point

No data available

Ignition temperature

No data available

Flammability

No data available

Lower explosion limit

No data available

Upper explosion limit

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No data available		
Vapour pressure		
No data available		
Relative vapour density		
No data available		
Relative density		
No data available		
Density		
No data available		
Solubility in water		
Reference temperature	20	°C
Comments	soluble	
Solubility		
No data available		
Partition coefficient n-octanol/water (log value)		
No data available		
Kinematic viscosity		
No data available		
Particle characteristics		
No data available		

9.2 Other information

Other information
No data available.

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

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions

None, when used as directed.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

Product reacts with: Zinc; Aluminium; iron; copper

10.6 Hazardous decomposition products

None, if handled according to intended use.

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

Acute oral toxicity
No data available
Acute dermal toxicity
No data available
Acute inhalational toxicity
No data available
Skin corrosion/irritation

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No data available

Serious eye damage/irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Reproduction toxicity

No data available

Carcinogenicity

No data available

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Aspiration hazard

No data available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Frequent persistent contact with the skin can cause skin irritation.

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

No data available.

Other information

No data available.

SECTION 12: Ecological information**12.1 Toxicity****Toxicity to fish (acute)**

No data available

Toxicity to fish (chronic)

No data available

Toxicity to Daphnia (acute)

No data available

Toxicity to Daphnia (chronic)

No data available

Toxicity to algae (acute)

No data available

Toxicity to algae (chronic)

No data available

Bacteria toxicity

No data available

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

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Results of PBT and vPvB assessment	
PBT assessment	No data available.
vPvB assessment	No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

12.8 Other information

Other information
Do not discharge product unmonitored into the environment.
Do not discharge into drains or waters and do not dispose of in public landfills.

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

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residues must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information**14.1 Transport ADR/RID/ADN**

Class	9
Classification code	M6
Packing group	III
Hazard identification no.	90
UN number	UN3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Technical name	Poly(hexamethylenebiguanide) hydrochloride
Tunnel restriction code	-
Label	9
Environmentally hazardous substance mark	Symbol "fish and tree"

14.2 Transport IMDG

Class	9
Packing group	III
UN number	UN3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Technical name	Poly(hexamethylenebiguanide) hydrochloride
EmS	F-A, S-F
Label	9
Marine pollutant mark	Symbol "fish and tree"

14.3 Transport ICAO-TI / IATA

Class	9
Packing group	III
UN number	UN3082
Proper shipping name	Environmentally hazardous substance, liquid, n.o.s.
Technical name	Poly(hexamethylenebiguanide) hydrochloride
Label	9
Environmentally hazardous substance mark	Symbol "fish and tree"

14.4 Other information

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No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Maritime transport in bulk according to IMO instruments

Not relevant

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulations****Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

The product is considered being subject to REACH regulation (EC) 1907/2006 annex XVII.	No 3
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The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

No	Substance name	CAS no.	EC no.	No
1	Poly(hexamethylenebiguanide) hydrochloride	27083-27-8	-	75

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is subject to Part I of Annex I, risk category:	E2
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15.2 Chemical safety assessment

No data available.

SECTION 16: Other information**Sources of key data used to compile the data sheet:**

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Creation of the safety data sheet

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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