Safety Data Sheet

according to Regulation (EC) No 1907/2006

S-LYS (SpheroLyse VER 1.0)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

S-LYS (SpheroLyse VER 1.0)

Further trade names

Article No.: 007-014-51796

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

Use of the substance/mixture

Scientific research and development, in vitro diagnostic medical devices

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	

1.4. Emergency telephone number:

Only from Malta: 112

Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Additional advice on labelling

Labelling according to national medical devices regulations.

2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria. No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Relevant ingredients

none (according to Regulation (EC) No 1907/2006 (REACH))

Further Information

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

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

After contact with skin

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

After contact with eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

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

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

No known symptoms to date.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2). Dry extinguishing powder. Alcohol resistant foam. Water spray

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide (CO2).

5.3. Advice for firefighters

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

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

No special measures are necessary.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. (See section 8.)

Advice on protection against fire and explosion

Usual measures for fire prevention.

Advice on general occupational hygiene

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

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

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

Hints on joint storage

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

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.
Recommended storage temperature: 2-8°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
26628-22-8	Sodium azide	-	0.1		TWA (8 h)	
		-	0.3		STEL (15 min)	

8.2. Exposure controls

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN ISO 16321-1:2022

Hand protection

In case of prolonged or frequently repeated skin contact:
Wear suitable gloves.
Suitable material:
FKM (fluororubber). - Thickness of glove material: 0,4 mm
Breakthrough time >= 8 h
Butyl rubber. - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm
Breakthrough time >= 8 h
PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
The selected protective gloves have to satisfy the specifications of EU Directive EC/ 2016/425 and the standard EN 374 derived from it.
Before using check leak tightness / impermeability. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab apron.

Respiratory protection

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

Thermal hazards

No special precautionary measures are necessary.

Environmental exposure controls

No special precautionary measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless
Odour:	characteristic
Odour threshold:	not determined

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not relevant
pH-Value:	7,5 - 8,0
Viscosity / kinematic:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Dissolution rate:	not relevant
Partition coefficient n-octanol/water:	not relevant
Dispersion stability:	not relevant
Vapour pressure:	not determined
Density:	not determined

Bulk density:	not relevant
Relative vapour density:	not determined
Particle characteristics:	not relevant

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

none

Sustained combustibility:	No sustained combustibility

Self-ignition temperature

Solid:	not relevant
Gas:	not relevant

Oxidizing properties

none

Other safety characteristics

Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Sublimation point:	not relevant
Softening point:	not relevant
Pour point:	not relevant
Viscosity / dynamic:	not determined
Flow time:	not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.
Refer to section 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidising agent, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, metabolism and distribution

No data available.

Acute toxicity

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

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Specific effects in experiment on an animal

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.7. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

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

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of these transport regulations.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

refer to section 6 - 8

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 regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Directive 2010/75/EU on industrial emissions:	not determined
Directive 2004/42/EC on VOC in paints and varnishes:	not determined
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)
This mixture is classified as not hazardous according to Regulation (EC) 1272/2008 [CLP].
REACH 1907/2006 Appendix XVII, No (mixture): not relevant

National regulatory information

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

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Rev. 1,0; Initial release: 05.07.2021, 01.06.2015
Rev. 2,0; Revision: 30.04.2024

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European LIst of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue
IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
PNEC: predicted no effect concentration
PBT: Persistent bioaccumulative toxic
RID: Reglement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
REACH: Registration, Evaluation, Authorisation of Chemicals
SVHC: substance of very high concern
TRGS: Technische Regeln für Gefahrstoffe
UN: United Nations
VOC: Volatile Organic Compounds
WGK: Water Hazard Class (Germany)

Further Information

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

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