

Microgen Staph Latex Kit (Cat. nr. M43)

SECTION 1: Identification of the substance/preparation and of the Company/Undertaking

1.1. Product identifier

Product name

Microgen Staph Latex Kit

Cat. Nr.:

M43

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

Rapid slide agglutination test for the confirmatory identification of presumptive *Staphylococcus aureus* colonies from primary plate culture.

1.3. Details of the supplier of the safety data sheet

Gold Standard Diagnostics Budapest Kft.

Fóti út 56/A.

1047 BUDAPEST

HUNGARY

Contact information: www.goldstandarddiagnostics.com/contacts

Phone: + 36 20 457 1204

Responsible person: E-mail: CustomerService.Bud@eu.goldstandarddiagnostics.com

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Not classified.

For the full text of H-statements mentioned in this Section: see Section 16.

2.2. Label elements

Hazard Pictograms:

-

Signal word:

-

Hazard statements:

-

Precautionary statements:

-

Supplemental hazard information:

-

Substances contributing of hazard identification:

-

2.3. Other hazards:

See PBT and vPvB assesment results in section 12.5.

Endocrine disrupting properties: see sections 11.2. and 12.6.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

The kit contains: M43A Staph Test Latex and M43B Positive Control

All contain the following hazardous component:

Component	CAS No.	EC-No.	Index-No.	REACH-No.	Concentration	Classification according to Regulation (EC) No. 1272/2008 [CLP]	H- statements	Special concentration limits/M-factor/ATE
Sodium azide	26628-22-8	247-852-1	011-004-00-7	-	0,099	Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	H300 H400 H410 EUH032	-

For the full text of H-statements mentioned in this Section: see Section 16.

The product does not contain Substances of Very High Concern (SVHC).

SECTION 4: First Aid Measures

4.1. Description of first aid measures:

GENERAL INFORMATION:

In case of accident or feeling sick immediately consult a physician. Show this safety data sheet or the product label to the doctor in attendance!

Eye –washing and skin-washing facilities should be available at the workplace for specific and immediate treatment.

FOLLOWING INGESTION:

If chemical has been swallowed, wash out mouth with water. Do not swallow mouthwash. Seek medical advice.

FOLLOWING INHALATION:

Move to fresh air.

FOLLOWING SKIN CONTACT

Wash off immediately with soap and plenty of water. In case of irritation consult a physician.

FOLLOWING EYE CONTACT:

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

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

No information available.

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

Treat symptoms.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Suitable extinguishing media : use agent most appropriate to extinguish surrounding fire. Water spray, dry chemical or CO₂.

Unsuitable extinguishing media : water jet, foam.

5.2. Special hazards arising from the substance or mixture

Substance is non-flammable.

Thermal decomposition can lead to release of irritating gases and vapours.

5.3. Advice for firefighters

Protective equipment: Wear self-contained breathing apparatus pressure-demand, and full protective gear.

Collect contaminated firefighting water separately. It must not enter the sewage system. It should be disposed of according to local regulations.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Ensure adequate ventilation. Wear appropriate personal protective equipment. Wear disposable vinyl/nitrile gloves. Avoid contact with skin, eyes and clothing.

For emergency personnel

Ensure adequate ventilation. Wear appropriate personal protective equipment. Wear disposable vinyl/nitrile gloves. Avoid contact with skin, eyes and clothing.

See sections 7 and 8.

6.2. Environmental precautions

Should not be released into the environment. Do not let it enter into surface water or sanitary sewer system.

6.3. Methods and materials for containment and cleaning up

Soak up with inert absorbent (dry earth, sand or other non-combustible material) material. Disposal: see section 13. Clean contaminated surface thoroughly. Properly disinfect any spills. Test specimens require decontamination with bleach solution or appropriate germicide prior to pick up.

6.4. Reference to other sections

See sections 7, 8 and 13

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

For In vitro diagnostic use only. Read the Instructions for Use. Always follow Good Laboratory Practice when using this product
Avoid contact with eyes, skin and clothing.
Advice on protection against fire and explosion: Normal measures for preventive fire protection

7.2. Conditions for safe storage, including any incompatibilities

Store at 2-8°C. Keep all containers tightly closed until ready to use. Under these conditions reagents will retain their activity until the expiry date shown on the label on outer carton.

7.3. Specific end use(s)

No information available.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Exposure limit values

Source GESTIS

Sodium azide

CAS-No.: 26628-22-8

Remark: as NaN₃

Country	Limit value - TWA			Limit value - STEL		
	ppm	mg/m ³	F/cm ³	ppm	mg/m ³	F/cm ³
Austria		0,1 (1)			0,3 (1)(2)	
Remarks:						
(1) Skin						
(2) 15 minutes average value						
Belgium		0,1 (1)(2)			0,3 (1)(2)(3)	
Remarks:						
(1) Additional indication "D" means that the absorption of the agent through the skin, mucous membranes or eyes is an important part of the total exposure. It can be the result of both direct contact and its presence in the air.						
(2) Additional indication "M" means that irritation occurs when the exposure exceeds the limit value or there is a risk of acute poisoning. The work process must be designed in such a way that the exposure never exceeds the limit value. For evaluation, the sampled period should be as short as possible. However, the sampled period shall be long enough to perform a reliable measurement. The measured result shall be related to the considered period.						
(3) 15 minutes average value						
Denmark		0,1 (1)			0,2 (1)(2)	
Remarks:						
(1) Skin						
(2) 15 minutes average value						
European Union		0,1 (1)			0,3 (1)(2)	

General remarks:

Bold-type: Indicative occupational exposure limit value (IOELV)

Remarks:

- (1) Skin
- (2) 15 minutes average value

Finland 0,1 0,3 (1)

Remarks:

- (1) 15 minutes average value

France 0,1 (1) 0,3 (1)(2)

General remarks:

Bold type: Restrictive statutory limit values

Remarks:

- (1) Skin
- (2) 15 minutes average value

Germany (AGS) 0,2 0,4 (1)

Remarks:

- (1) 15 minutes average value

Germany (DFG) 0,2 (1) 0,4 (1)(2)

Remarks:

- (1) Inhalable fraction
- (2) 15 minutes average value

Hungary 0,1 0,3 (1)

Remarks:

- (1) 15 minutes average value

Ireland 0,1 0,3 (1)

Remarks:

- (1) 15 minutes reference period

Italy 0,1 (1) 0,3 (1)(2)

Remarks:

- (1) Skin
- (2) 15 minutes average value

Latvia 0,1 0,3 (1)

Remarks:

- (1) 15 minutes average value

Norway 0,1 0,3 (1)

Remarks:

- (1) 15 minutes average value

Romania 0,1 0,3 (1)

Remarks:

- (1) 15 minutes average value

Spain 0,1 (1) 0,3 (1)(2)

Remarks:

- (1) Skin
- (2) 15 minutes average value

Sweden	0,1	0,3 (1)
Remarks: (1) 15 minutes average value		
The Netherlands	0,1 (1)	0,3 (1)(2)
Remarks: (1) Skin (2) 15 minutes average		

Recommended monitoring procedures: Methods for measurement of the workplace atmosphere have to correspond to the requirements of norms DIN EN 482 and DIN EN 689

8.2. Exposure controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Caution is necessary to prevent skin contact, eye contact, cloth contact and spilling into the floor.

5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers exposed to chemical pathogenic factors, pursuant to Section 11(2) in the case of hazardous substances not regulated by limit values, the employer is obliged to reduce the level of exposure to the lowest level expected according to scientific and technical standards, at which level, according to the current state of science, the dangerous substance has no health-damaging effect. When using in an open system, use local exhaust where possible. If local extraction is not possible or is insufficient, adequate ventilation of the work area must be ensured.

General protective and hygienic measures

Do not eat, drink or smoke when using this product. Wash hands after using the product.

Appropriate engineering controls

Handle in a fume cupboard or under local exhaust ventilation.

Individual protection measures, such as personal protective equipment:



a) eye/face protection

Safety eyewear or face protection complying with an approved standard (European Standard EN 166) should be used. Safety glasses with shields.

b) skin protection

- i. hand protection: Chemical-resistant, impervious gloves complying with an approved standard (European Standard EN374) should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- ii. other: body protection: Laboratory coat.

c) respiratory protection

Respiratory protection is not required under normal and intended conditions of use.

d) thermal hazards

None.

Environmental exposure controls

Do not let product enter drains.

Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration and ventilation. Information on the selection of protective equipment for use with this material, as provided above, is based upon intended, normal usage. If there is different than normal usage of the material it is advised to consult a safety specialist about the type of personal protective equipment and other actions that should be taken.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance M43A Staph Latex: aqueous suspension; M43B Positive Control: Suspension

Color M43A Staph Latex: Milky white

Odor Not available

Odor threshold Not available

Melting point/freezing point Not available

Initial boiling point and boiling range Not available

Flammability Not flammable.

Upper/lower flammability or explosive limits Not available

Flash point Not available

Auto-ignition temperature Not available

Decomposition temperature Not available

pH Not available

Kinematic viscosity Not available

Solubility Not available

Partition coefficient: n-octanol/water Not available

Vapor pressure Not available

Density and/or relative density Not available

Relative vapor density Not available

Particle characteristics Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not classified.

9.2.2. Other safety characteristics

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions. Do not use after stated expiry date. Store at 2-8°C .

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid contact with lead or copper plumbing.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

None under normal use conditions.

SECTION 11: Toxicological Information

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

Acute toxicity:

No information available.

Skin corrosion / irritation:

No information available.

Serious eye damage/irritation:

No information available.

Respiratory or skin sensitization:

No information available.

Germ cell mutagenicity:

No information available.

Carcinogenicity:

No information available.

Reproductive toxicity:

No information available.

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

No information available.

Relevant toxicological data:

No information available.

Information on likely routes of exposure:

No information available.

Symptoms related to the physical, chemical and toxicological characteristics:

Skin contact: No specific information available.

Eye contact: No specific information available.

Inhalation: No specific information available.

Ingestion: No specific information available.

Other: No information available.

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

See section 4.2.

Interactive effects:

No information available.

Absence of specific data:

No information available.

Mixtures:

No information available.

Mixture versus substance information:

No information available.

11.2 Information on other hazards

Endocrine disrupting properties

None of the components are listed.

Other information

No information available.

SECTION 12: Ecological Information

Do not allow product to reach surface water, waterways or soil.

12.1 Toxicity

No information available.

12.2. Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Endocrine disrupting properties

None of the components are listed.

12.7. Other adverse effects

No further relevant information available.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

Product disposal:

Dispose of contents in accordance with local/regional/national/international regulations.

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Packaging disposal:

Dispose of container in accordance with local/regional/national/international regulations.

Physical, chemical properties, which could influence waste management:

No information available.

Sewage disposal-relevant information:

No information available.

SECTION 14: Transport Information

Product is not classified as a dangerous good for transport.

ADR/RID

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

ADN:

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

IMDG

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user:-

ICAO-TI/IATA-DGR

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

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 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

15.2. Chemical safety assessment:

Chemical safety assessment has not been carried out for this product.

SECTION 16: Other information

Identification of changes

Rev: 02 Revision and harmonization of the data sheet in accordance with applicable international legislation.

Abbreviations and acronyms:

ATE: Acute Toxicity Estimate. PBT: persistent, bioaccumulative and toxic. vPvB: very persistent, very bioaccumulative. LD50 lethal dose, LC50 Lethal concentration. EC50 Effective concentration. EWC: European Waste Catalog. IARC: International Agency for Research on Cancer. RTECS: Registry of Toxic Effects of Chemical Substances. VOC: Volatile Organic Carbon. PNEC: Predicted no effect concentration. LFL: Lower Inflammatory Limit. UFL: Upper Flammability Limit. LEL lower explosion limit. UEL: Upper explosion limit. STOT: Specific Target Organ Toxicity. LDLo Lethal dose, low. IC50: Inhibitory concentration. SVHC: Substances of very high concern. NOAEL: No-observed-adverse-effect level. LOAEL: Lowest-observed-adverse-effect level

Full text of H-statements from section 2 and 3:

H300 – Fatal if swallowed.

H400 – Very toxic to aquatic life.

H410 – Very toxic to aquatic life with long lasting effects.

EUH 032 – Contact with acids liberates very toxic gas.

Precautionary statements:

-

Further training advice:

No information available.

Recommended restrictions on use:

This product is intended to be used for laboratory use only by technical staff trained in microbiological techniques. Classification and labelling have been performed according to CLP Regulations.

Read the Instructions for Use for further information on limitations of use.

This Safety Data Sheet was prepared on the basis of documentation provided by the manufacturer and complies with the requirements of Regulation (EC) No. 878/2020

The above information is based on data available and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determinations of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty or guarantee, expressed or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.