



SAFETY DATA SHEET *According to Regulation (EC) No 1907/2006 (REACH)*

AND REGULATION (EU) 2015/830

Product Name	MAGLUMI [®] SARS-CoV-2 S-RBD IgG (CLIA)
REF	130219017M (100 tests) 130619017M(50 tests)
Components	Magnetic Microbeads
	Calibrator Low
	Calibrator High
	Buffer
	ABEI Label
	Diluent
	Control 1
	Control 2

Revision No.: V1

Release Date: 5th Aug, 2020

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name	MAGLUMI® SARS-CoV-2 S-RBD IgG (CLIA)
Product code	130219017M (100 tests) 130619017M(50 tests)
Product type	Liquid

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

Relevant identified uses	In vitro diagnostic agent
Uses advised against	For professional users only

1.3 Details of the supplier of the safety data sheet

Supplier	Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.)
Address	No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China
Telephone	+86-755-21536601
Fax	+86-755-28292740
E-mail	register@snibe.com

1.4 National contact Shanghai International Holding Corp. GmbH (Europe)

Address	Eiffestrasse 80, 20537 Hamburg, Germany
Telephone	+49-40-2513175
Fax	+49-40-255726
Emergency Telephone number	+86-755-21536601
Opening hour	Only available during office hours.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) no 1272/2008 (CLP)	This product has been evaluated according to the classification criteria of Regulation (EC) no. 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). This product does not meet the classification criteria established by the CLP or those established by the GHS.
---	--

2.2 Label elements

The product is not subject to labeling according to the classification criteria of Regulation (EC) no. 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Pictogram	None
Signal word	None
Hazard statements	None

Precautionary statements None

2.3 Other hazards

Other hazards This mixture do not meet the criteria for PBT and vPvB

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Composition

Composition A multi-component diagnostic kit, containing Magnetic Microbeads, Calibrator High, Calibrator low, Buffer, ABEI Label, Positive Control and Negative Control.

3.2 Hazardous ingredients

Substance / Mixtures: Mixtures

Component	N. CAS	N. EINECS	Concentration	CLP Classification -1272/2008/EC
Sodium azide	26628-22-8	247-852-1	0.09%	Acute Tox.2;H300 Aquatic Acute 1;H400 Aquatic Chronic 1;H410 EUH032

Further information: For the full text of the hazard statements (H) and the precautionary statements (P), refer to section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first-aid measures

- Eye contact** Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs
- Skin contact** Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Inhalation** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Ingestion** Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

4.2 Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physician No other information is available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Unsuitable extinguishing media High volume water jet

5.2 Special hazards arising from the substance or mixture

Reacts with copper, lead, silver, mercury and carbon disulfide to form compounds particularly sensitive to impacts.

5.3 Advice for firefighters

Special protective actions for fire-fighters Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Further information: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

6.2 Environmental precautions

Environmental precautions Prevent from entering sewage system, storm drains, surface waters, and soil.

6.3 Methods and material for containment and cleaning up

Methods for Containment Wipe up with absorbent material (e.g. cloth, fleece). Pick up and transfer to properly labeled containers.

Methods for Cleaning Up Clean with disinfectants. Clean contaminated surface thoroughly.

6.4 Reference to other sections

Reference sections See Sections 8 & 13 for additional information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling Wear personal protective equipment. See section 8. Avoid contact with skin, eyes and clothing. Remove and wash contaminated clothing before re-use. Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Storage In accordance with the norms generally accepted for chemicals in laboratories. Store in original manufacturer containers. Store in closed containers at temperatures compatible with the information provided on the label. Protect against light. Protect containers from damage. Keep away from food and animal feed..

Incompatible Products See section10.

7.3 Specific end uses

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Substance	Sodium azide				
CAS Number	26628-22-8				
Country	Limit value-Eight hours		Limit value-Short term		Legal basis
	ppm	mg/m ³	ppm	mg/m ³	
<u>Austria</u>	-	0.1	-	0.3	<u>Grenzwerte für Arbeitsstoffe und über krebserzeugende Arbeitsstoffe</u> (Grenzwerteverordnung 2007 - GKV 2007)
<u>Belgium</u>	-	0.1	-	0.3	<u>Annex 1</u> of the <i>Arrêté royal du 11 mars 2002 relatif à la protection de la santé et de la sécurité des travailleurs contre les risques liés à des agents chimiques sur le lieu de travail.</i>
Denmark	-	0.1	-	0.2	<u>Grænseværdier for stoffer og materialer</u>
European Union	-	0.1	-	0.3	COMMISSION DIRECTIVE 2000/39/EC
Finland	-	0.1	-	0.3(1)	<u>Finnish Ministry of Social Affairs and Health</u>
<u>France</u>	-	0.1	-	0.3	<u>Order of 9 February 2006</u> <u>Decree No. 2006-133</u>
<u>Germany (AGS)</u>	-	0.2	-	0.4(1)	<u>TRGS 900</u> : Occupational exposure limits (Arbeitsplatzgrenzwerte).
<u>Germany (DFG)</u>	-	0.2 inhalable aerosol	-	0.4 inhalable aerosol	<u>TRGS 900</u> : Occupational exposure limits (Arbeitsplatzgrenzwerte).
<u>Hungary</u>	-	0.1	-	0.3	Ordinance No.25/2000, of 30 Sept., concerning the chemical safety of workplaces
<u>Ireland</u>	-	0.1	-	0.3(1)	Schedule 1 to the 2002 <i>Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001.</i>
Italy	-	0.1	-	0.3	-
Latvia	-	0.1	-	0.3(1)	-
<u>Poland</u>	-	0.1	-	0.3	<u>Workplace Safety and Health (General Provisions) Regulations 2006</u>
<u>Spain</u>	-	0.1	-	0.3	<u>Límites de exposición profesional para agentes químicos en España</u> (2008)
<u>United Kingdom</u>	-	0.1	-	0.3	Health and Safety Executive (HSE) Guidance Note EH40 <u>Workplace exposure limits</u>
Remarks					
Australia	(1) Ceiling limit value (2) For the two substances marked with this footnote (Benomyl, and Sodium azide), the exposure standards are established as gravimetric (mg/m ³) values and converted into volumetric values.				
European Union	Bold-type: Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure				
Finland	(1) 15 minutes average value				
France	Bold type: Restrictive statutory limit values				
Germany (AGS)	(1) 15 minutes average value				
Germany (DFG)	STV 15 minutes average value				
Ireland	(1) 15 minutes reference period				
Italy	skin				
Latvia	(1) 15 minutes average value				
Spain	skin				

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Engineering Measures Showers
 Eye wash stations and suitable ventilation systems to keep air concentrations low.

8.2.2 Individual protection measures

Hygiene measures Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and showers are close to the workstation location.

Eye/face protection Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin and Body Protection Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Personal protective equipment for the body should be selected based on the task being performed and the risks involved before handling this product.

Respiratory Protection Use reagent in well-ventilated rooms

Environmental exposure control No information available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

	Magnetic microbeads	Calibrator High	Calibrator Low	Buffer	ABEI Label	Diluent	Control 1	Control 2
The physical state	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
Color	Brown	Colourless	Colourless	Light yellow	Colourless	Colourless	Colourless	Colourless
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Odour threshold	No data available	No data available	No data available	No data available	No data available	No data available	No data available	No data available
pH	6.85	6.85	6.85	7.45	8.12	7.42	6.85	6.85
Melting point/freezing point	No data available	No data available	No data available	No data available	No data available	No data available	No data available	No data available
Initial boiling point and boiling range	No data available	No data available	No data available	No data available	No data available	No data available	No data available	No data available
Flash point	No data available	No data available	No data available	No data available	No data available	No data available	No data available	No data available
Evaporation rate	No data available	No data available	No data available	No data available	No data available	No data available	No data available	No data available
Flammability (solid, gas)	No data available	No data available	No data available	No data available	No data available	No data available	No data available	No data available

Shenzhen New Industries Biomedical Engineering Co., Ltd

www.snibe.com

Upper/lower flammability or explosive limits	No data available							
Vapour pressure	No data available							
Vapour density	No data available							
Relative density	No data available							
Solubility(ies)	No data available							
Partition coefficient: n-octanol/water	No data available							
Auto-ignition temperature	No data available							
Decomposition temperature	No data available							
Viscosity	No data available							
Explosive properties	No data available							
Oxidising properties	No data available							

9.2 Other information

Other information No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	Not reactive under normal conditions.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	Avoid direct sunlight and extremes of high temperature.
Incompatible materials	Strong acid materials and strong oxidizing agents.
Hazardous decomposition products	None under normal use conditions

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium azide	= 27 mg/kg (Rat)	= 20mg/kg(Rabbit) = 50 mg/kg (Rat)	-

Symptoms	No data available
Skin corrosion/irritation	No data available
Serious eye damage/eye irritation	No data available
Sensitization	No data available
Mutagenic effects	No data available
Carcinogenic effects	No data available
Reproductive toxicity	No data available
STOT-single exposure	No data available
STOT-repeated exposure	No data available
Aspiration Hazard	No data available
Other information	No data available

11.2 Information on likely routes of exposure

Inhalation	Limited inhalation hazard at normal work temperatures.
Eye Contact	May cause irritation.
Skin Contact	Causes skin irritation. May cause sensitization by skin contact.
Ingestion	No harmful effects expected in amounts likely to be ingested by accident.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
Sodium azide	EC50 0.35 mg/L (Pseudokirchneriella subcapitata) 96 h	LC50 0.8 mg/L (Oncorhynchus mykiss) 96 h ; LC50 5.46 mg/L (Pimephales promelas) 96 h ; LC50 0.7 mg/L (Lepomis macrochirus) 96 h	LC100 1 mg/L (Orconectes rusticus) 96 h

12.2 Persistence and degradability

Products	No data available
----------	-------------------

12.3 Bioaccumulative potential

Products	No data available
----------	-------------------

12.4 Mobility in soil

Shenzhen New Industries Biomedical Engineering Co., Ltd

www.snibe.com

Products	No data available
----------	-------------------

12.5 Results of PBT and vPvB assessment

Products	This mixture contains no components considered to be either persistent, bio -accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB) at levels of 0.1% or higher.
----------	---

12.6 Other adverse effects

Products	No data available
----------	-------------------

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

General information	Dispose of waste and residues in accordance with local authority requirements.
Disposal methods	Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Do not reuse empty containers. No contact with acids, heavy metals.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Not applicable. The product is not classified as dangerous goods for any mode of transport, according to the United Nations Model Regulations ADR, RID, AND, IMDG, ICAO.

14.2 UN proper shipping name

Not subject to the regulation of dangerous goods

14.3 Transport hazard class(es)

Not subject to the regulation of dangerous goods

14.4 Packing group

Not subject to the regulation of dangerous goods

14.5 Environmental hazards

Not subject to the regulation of dangerous goods

14.6 Special precautions for user

Not dangerous goods in the meaning of ADR/ , RID, AND, IMDG, ICA

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EU) No 649/2012	No component of the mixture is subject to REGULATION (EU) no. 649/2012
DIRECTIVE 96/82/EC	No component of this mixture is subject to DIRECTIVE 96/82 / EC

Shenzhen New Industries Biomedical Engineering Co., Ltd

www.snibe.com

DIRECTIVE 2008/105/EC	No component of this mixture is subject to DIRECTIVE 2008/105 / EC
REGULATION (EC) No 850/2004	This mixture does not contain persistent organic pollutants
REGULATION (EC) No 2037/2000	This mixture does not contain components that reduce the ozone layer

15.2 Chemical safety assessment

Chemical safety assessment

Chemical safety assessment reports are not required for mixtures/IVD products.

SECTION 16: OTHER INFORMATION

16.1 Date of issue/Date of revision

5th Aug, 2020

16.2 Abbreviations and acronyms

CAS=Chemical Abstracts Service (Division of the American Chemical Society)
IATA = International Air Transport Association
IMDG = International Maritime Dangerous Goods
ADR=European Agreement concerning the International Carriage of Dangerous Goods by Road
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
IBC = Intermediate Bulk Container
STOT=Specific target organ toxicity
LC50=Lethal concentration, 50 percent
LD50=Lethal dose, 50 percent
EC50 = half maximal effective concentration
TWE= the eight-hour time weighted average
STEL= short-term limits/excursion limits
ECHA= European Chemicals Agency

16.3 Key literature references and sources for data

This SDS was prepared on the basis of sheets of individual components, literature data, online databases (e.g. ECHA,) as well as our knowledge and experience, taking into account current legislation.

Online database:

GESTIS - International limit values for chemical agents (Occupational exposure limits, OELs).

16.4 Full text of abbreviated H statements

<i>Acute toxicity</i>	<i>Hazardous to the aquatic environment</i>
<i>GHS06</i>	<i>GHS09</i>
	

H300=Fatal if swallowed.

H400=Very toxic to aquatic life.

H410=Very toxic to aquatic life with long lasting effects

EUH032=Contact with acids liberates very toxic gas

16.5 Training advice

The employer shall develop an active training program of worker protection measures, which is specific to the individual workplace, and consider any measures which may be necessary to protect the environment.

16.6 Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The above information is believed to be correct but does not purport to be all inclusive and shall be used as a guide only. The information in this document is based on the present state of our

knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product and is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification.



SAFETY DATA SHEET *According to Regulation (EC) No 1907/2006 (REACH)*

Product Name	MAGLUMI Starter 1+2
Components	Starter 1
	Starter 2

Catalog Number	Specification
130299004M	230m l x3
130299012M	450ml x1

Revision No.: 006

Release Date: March 28, 2019



Section 1 Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier:

1.1.1 Mixtures

Designation of the Mixture: MAGLUMI Starter 1+2 (CLIA) Starter 1

1.1.2 Other means of identification: Not applicable

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

1.2.1 Relevant identified uses: For In Vitro Diagnostic Use

1.2.2 Uses advised against: Not available

1.3 Details of the supplier of the safety data sheet:

Supplier : Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.)

Address : No.16, Jinhui Road, Pingshan New District, 518122, Shenzhen, P.R.China

Telephone : +86-755-21536601

Fax : +86-755-28292740

E-mail : Registration_Dept@snibe.net

National contact : Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Telephone : +49-40-2513175

Fax : +49-40-255726

1.4 Emergency telephone number:

+86-755-21536601

Opening hour: Only available during office hours.

Section 2 Hazards Identification

2.1 Classification of the substance or mixture

Hazard classes/Hazard categories	Hazard statement
Skin irritation, Category 2	H315

2.2 Label elements

Mixtures: Starter 1

Hazard pictogram:

Exclamation mark



Signal Word: **Warning**

Hazard Statement: H315 Causes skin irritation.



Precautionary statements: P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+352 IF ON SKIN: Wash with plenty of soap and water.

P362+P364 Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

Not applicable

Section 3 Composition/Information on Ingredients

Substance/Mixture: Mixture

CAS No	EC No	Index No	REACH Registration No	%[weight]	Name	Classification according to Regulation (EC) No 1272/2008(CLP)
1310-73-2	215-185-5	011-002-00-6	/	1.5	Sodium hydroxide ; caustic soda	Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %

Additional information: For the wording of the listed relevant phrases and hazard statements, refer to section 16

Section 4 First Aid Measures

4.1 Description of first aid measures:

4.1.1 In case of inhalation:

Remove to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Maintain an open airway.

4.1.2 In case of skin contact:

Immediately and thoroughly wash with water or a suitable buffer solution. If necessary, a physician should be consulted.

4.1.3 In case of eyes contact:

Rinse the affected eye with widely spread lids for 15 minutes under running water whilst protecting the unimpaired eye.

4.1.4 In case of ingestion:

Induce vomiting. If the casualty is still conscious, rinse the mouth and spit the fluids out and drink copious amounts of milk or water. In the meantime call an emergency physician to the scene of the accident.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a doctor/physician.

Section 5 Fire-Fighting Measures



5.1 Extinguishing media: Use water spray, dry chemical, carbon dioxide, or appropriate foam.

5.2 Special hazards arising from the substance or mixture: May produce harmful toxic smoke.

5.3 Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes. During a fire, irritating and toxic gases may be generated by thermal decomposition or combustion.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Wear gloves and respirator to avoid direct contact with the leakage of fluid. Carefully sweep up, gather and remove. Avoid rising dust. Afterwards ventilate area and wash spill site.

6.1.2 For emergency responders:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods for containment and cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections: Refer to section 8 and 13 of the SDS.

Section 7 Handling and Storage

7.1 Precautions for safe handling:

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Keep container tightly closed.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Store only in original container. Refer to the package insert or product label for additional information on storage conditions.

Further information on storage conditions: Refer to product label. Protect from heat and direct sunlight.

Advice on common storage: No materials to be especially mentioned.

Other data: No decomposition if stored and applied as directed.

7.3 Specific end use(s): The mixture is intended specifically for in vitro diagnostic use and shall be considered potentially able to transmit infectious agents. Handle in accordance with good laboratory practice (GLP).

Section 8 Exposure Controls/Personal Protection



8.1 Control parameters:

- 8.1.1 Occupational exposure limits: No data available.
- 8.1.2 Additional exposure limits under the conditions of use: No data available.
- 8.1.3 DNEL/DMEL and PNEC-Values: No data available.

8.2 Exposure controls:

- 8.2.1 Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.
- 8.2.2 Personal protective equipment:
 - 8.2.2.1 Eye/face protection: Protective eyeglasses or chemical safety goggles should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.
 - 8.2.2.2 Skin protection:
 - Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
 - Body protection: Protective clothing with elasticized cuffs and closed neck. Boots made of PVC.
 - 8.2.2.3 Respiratory protection: Make sure workplace is well ventilated otherwise use a suitable respirator.
- 8.2.3 Environmental exposure controls: Avoid discharge into the environment. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Section 9 Physical and chemical Properties

9.1 Information on basic physical and chemical properties

Appearance:	Liquid
Colour:	Colorless
Odour:	No data available
Odour threshold:	No data available
pH:	12 to 13
Melting point/range (°C):	No data available
Boiling point/range (°C) :	No data available
Decomposition temperature(°C):	No data available
Flash point (°C) :	No data available
Ignition temperature (°C) :	No data available
Vapour pressure (20°C) :	No data available
Vapour density:	No data available
Density(g/cm ³):	No data available
Relative density:	No data available
Water solubility (g/l) at 20°C :	No data available
Solubility(ies):	No data available
Partition coefficient	No data available
n-Octanol/Water (log Po/w) :	No data available



Viscosity, dynamic (20 °C) :	No data available
Explosives	Not available
Flammable gases	Not available
Flammable aerosols	Not available
Oxidising gases	Not available
Gases under pressure	Not available
Flammable liquids	Not available
Flammable solids	Not available
Self-reactive substances and mixtures	Not available
Pyrophoric liquids	Not available
Pyrophoric solids	Not available
Self-heating substances and mixtures	Not available
Substances or mixtures which, in contact with water emit flammable gases	Not available
Oxidising liquids	Not available
Oxidising solids	Not available
Organic peroxides	Not available
Metal corrosion	Not available

9.3 Other safety information:

Limiting oxygen concentration	Not available
Bulk density	Not available
Solubility in different media	Not available
Stability in organic solvents and identity of relevant degradation products	Not available
Evaporation rate	Not available
Conductivity	Not available
Surface tension	Not available
Dissociation constant in water (pKa)	Not available
Oxidation-reduction Potential	Not available
Fat solubility (solvent – oil to be specified)	Not available

Section 10 Stability and Reactivity

10.1 Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability: Stable under recommended temperatures and pressures.

10.3 Possibility of hazardous reactions: No data available.

10.4 Conditions to avoid: Incompatible materials, Strong oxidants.



10.5 Incompatible materials: Acids, water/moisture, organic materials.

10.6 Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions-- Sodium oxide.

Other decomposition products: no data available.

Section 11 Toxicological Information

11.1 Information on toxicological effects:

Acute toxicity: No specific data.

Skin corrosion/Irritation: skin Irritation

Serious eye damage/irritation: eye irritation.

Respiratory or skin sensitization: No specific data.

Carcinogenicity: No known significant effects or critical hazards.

Germ cell mutagenicity: No specific data.

Reproductive toxicity: No specific data.

STOT- single exposure: No specific data.

STOT-repeated exposure: No specific data.

Aspiration hazard: No specific data.

Section 12 Ecological Information

12.1 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.

12.5 Results of PBT&vPvB assessment: No data available.

12.6 Other adverse effects: No data available.

Section 13 Disposal Considerations

13.1 Waste treatment methods: The generation of waste should be avoided or minimized wherever possible.

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. The waste material must be burn and incinerated and the liquid waste must be purified by 5% sodium hypochlorite half an hour.

Contaminated packaging: Please refer to applicable local regulations.



Do not re-use empty containers.

13.1.1 Product / Packaging disposal:

Hazardous waste according to Waste Catalogue Ordinance (AVV): 18 01 06* chemicals consisting of or containing dangerous substances.

13.1.2 Additional information:

Hazardous waste: The classification of the product may meet the criteria for a hazardous waste.

Section 14: Transport Information

14.1. UN number

Not applicable. The product is not classified to be a dangerous good for any mode of transport, according to *UN Model Regulations ADR, RID, AND, IMDG, ICAO*.

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

Section 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EU) No 649/2012: No components of this mixture are subject to the REGULATION (EU) No 649/2012.

DIRECTIVE 96/82/EC: No components of this mixture are subject to the DIRECTIVE 96/82/EC.

DIRECTIVE 2008/105/EC: No components of this mixture are subject to the DIRECTIVE 2008/105/EC.

REGULATION (EC) No 850/2004: This mixture does not contain any persistent organic pollutants.

REGULATION (EC) No 2037/2000: This mixture does not contain any components that deplete the ozone layer.

Water Hazard Classes: No Water Hazard Classes.

Technical Instructions on Air Quality Control (TA-Luft): This mixture does not contain any hazardous air pollutants.

15.2. Chemical Safety Assessment

Not applicable.

Section 16: Other Information

- (i) Indication of changes



Version	Changes	Date
Version 006	Add a new catalog number; change the national contact; revise the document format according to Regulation (EC) No 1907/2006 (REACH)	March 28, 2019

(ii) Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Dangerous Goods

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air

(iii) Key literature references and sources for data

REGULATION (EC) No 1272/2008, Regulation (EC) No 1907/2006 (REACH)

(iv) Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

(v) Relevant H-statements (number and full text)

H314: causes severe skin burns and eye damage

H315: causes skin irritation

H319: causes eye irritation

(vi) Training advice

The employer develop an active training programme of worker protection measures, and consider any measures which may be necessary to protect the environment.

(vii) Further information

The information provided in this Material 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 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.



Section 1 Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier:

1.1.1 Mixtures

Designation of the Mixture: MAGLUMI Starter 1+2 (CLIA) Starter 2

1.1.2 Other means of identification: Not applicable

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

1.2.1 Relevant identified uses: For In Vitro Diagnostic Use

1.2.2 Uses advised against: Not available

1.3 Details of the supplier of the safety data sheet:

Supplier : Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.)

Address : No.16, Jinhui Road, Pingshan New District, 518122, Shenzhen, P.R.China

Telephone : 0086-755-21536601

Fax : 0086-755-28292740

E-mail : Registration_Dept@snibe.net

National contact : Lotus Global Co., Ltd.

Address: 1 Four Seasons Terrace, West Drayton, Middlesex London, UB7 9GG, United Kingdom

Telephone : 0044-20-75868010

Fax : 0044-20-79006187

1.4 Emergency telephone number:

0086-755-21536601

Opening hour: Only available during office hours.

Section 2 Hazards Identification

2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

The product does not require any hazard warnings according to Regulation (EC) 1272/2008.

2.3 Other hazards

Section 3 Composition/Information on Ingredients

Substance/Mixture: Mixture

CAS No	EC No	Index No	REACH No	%[weight]	Name	Classification according to Regulation (EC) No 1272/2008(CLP)
7722-84-1	231-765-0	008-003-00-9	-	0.21	Hydrogen peroxide	This product does not meet the criteria for classification in any



						hazard class according to Regulation (EC) No 1272/2008
--	--	--	--	--	--	--

Section 4 First Aid Measures

4.1 Description of first aid measures:

4.1.1 In case of inhalation:

Remove to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Maintain an open airway.

4.1.2 In case of skin contact:

Immediately cleanse the affected skin areas with soap under running water.

4.1.3 In case of eyes contact:

Rinse the affected eye with widely spread lids for 15 minutes under running water whilst protecting the unimpaired eye.

4.1.4 In case of ingestion:

Induce vomiting. If the casualty is still conscious, rinse the mouth and spit the fluids out and drink copious amounts of milk or water. In the meantime call an emergency physician to the scene of the accident.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a doctor/physician.

Section 5 Fire-Fighting Measures

5.1 Extinguishing media: Use water spray, dry chemical, carbon dioxide, or appropriate foam.

5.2 Special hazards arising from the substance or mixture: No data available.

5.3 Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes. During a fire, irritating and toxic gases may be generated by thermal decomposition or combustion.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Wear gloves and respirator to avoid direct contact with the leakage of fluid. Carefully sweep up, gather and remove. Avoid rising dust. Afterwards ventilate area and wash spill site.

6.1.2 For emergency responders:

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for information on disposal.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter

drains.

6.3 Methods for containment and cleaning up: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.4 Reference to other sections: Refer to section 8 of the SDS.

Section 7 Handling and Storage

7.1 Precautions for safe handling:

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Keep container tightly closed.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Store only in original container. Refer to the package insert or product label for additional information on storage conditions.

Further information on storage conditions: Refer to product label. Protect from heat and direct sunlight.

Advice on common storage: No materials to be especially mentioned.

Other data: No decomposition if stored and applied as directed.

7.3 Specific end use(s): The mixture is intended specifically for in vitro diagnostic use and shall be considered potentially able to transmit infectious agents. Handle in accordance with good laboratory practice (GLP).

Section 8 Exposure Controls/Personal Protection

8.1 Control parameters:

8.1.1 Occupational exposure limits: No data available.

8.1.2 Additional exposure limits under the conditions of use: No data available.

8.1.3 DNEL/DMEL and PNEC-Values: No data available.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.

8.2.2 Personal protective equipment:

8.2.2.1 Eye/face protection: Protective eyeglasses or chemical safety goggles should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

8.2.2.2 Skin protection:

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection: Protective clothing with elasticized cuffs and closed neck. Boots made of PVC.

8.2.2.3 Respiratory protection: Make sure workplace is well ventilated otherwise use a suitable respirator.

8.2.3 Environmental exposure controls: Avoid discharge into the environment. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Section 9 Physical and chemical Properties**9.1 Information on basic physical and chemical properties**

Appearance:	Liquid
Colour:	Colorless
Odour:	No data available
Odour threshold:	No data available
pH:	7 to 8
Melting point/range (°C):	No data available
Boiling point/range (°C) :	No data available
Decomposition temperature(°C):	No data available
Flash point (°C) :	No data available
Ignition temperature (°C) :	No data available
Vapour pressure (20°C) :	No data available
Vapour density:	No data available
Density(g/cm ³):	No data available
Relative density:	No data available
Water solubility (g/l) at 20°C :	No data available
Solubility(ies):	No data available
Partition coefficient	No data available
n-Octanol/Water (log Po/w) :	No data available
Viscosity, dynamic (20 °C) :	No data available
Explosives	Not available
Flammable gases	Not available
Flammable aerosols	Not available
Oxidising gases	Not available
Gases under pressure	Not available
Flammable liquids	Not available
Flammable solids	Not available
Self-reactive substances and mixtures	Not available
Pyrophoric liquids	Not available
Pyrophoric solids	Not available
Self-heating substances and mixtures	Not available
Substances or mixtures which, in contact with water emit flammable gases	Not available
Oxidising liquids	Not available
Oxidising solids	Not available
Organic peroxides	Not available
Metal corrosion	Not available

9.2 Other safety information:



Limiting oxygen concentration	Not available
Bulk density	Not available
Solubility in different media	Not available
Stability in organic solvents and identity of relevant degradation products	Not available
Evaporation rate	Not available
Conductivity	Not available
Surface tension	Not available
Dissociation constant in water (pKa)	Not available
Oxidation-reduction Potential	Not available
Fat solubility (solvent – oil to be specified)	Not available

Section 10 Stability and Reactivity

10.1 Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability: Stable under recommended temperatures and pressures.

10.3 Possibility of hazardous reactions: No data available.

10.4 Conditions to avoid: Avoid excess heat.

10.5 Incompatible materials: No data available.

10.6 Hazardous decomposition products: Decomposes to water and oxygen.

Section 11 Toxicological Information

11.1 Information on toxicological effects:

Acute toxicity: No specific data.

Skin corrosion/Irritation: No specific data.

Serious eye damage/irritation: No specific data.

Respiratory or skin sensitization: No specific data.

Carcinogenicity: No known significant effects or critical hazards.

Germ cell mutagenicity: No specific data.

Reproductive toxicity: No specific data.

STOT- single exposure: No specific data.

STOT-repeated exposure: No specific data.

Aspiration hazard: No specific data.

Section 12 Ecological Information

12.1 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.

12.5 Results of PBT&vPvB assessment: No data available.

12.6 Other adverse effects: No data available.

Section 13 Disposal Considerations

13.1 Waste treatment methods: Waste generators must determine whether a discarded contents/container is classified as a hazardous waste. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Contaminated packaging: Please refer to applicable local regulations.

Do not re-use empty containers.

13.1.1 Product / Packaging disposal:

Hazardous waste according to Waste Catalogue Ordinance (AVV): 18 01 06* chemicals consisting of or containing dangerous substances.

13.1.2 Additional information:

Hazardous waste: The classification of the product may meet the criteria for a hazardous waste.

Section 14 Transport Information

14.1. UN number

Not applicable. The product is not classified to be a dangerous good for any mode of transport, according to *UN Model Regulations ADR, RID, AND, IMDG, ICAO*.

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

Section 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EU) No 649/2012: No components of this mixture are subject to the REGULATION (EU) No 649/2012.

DIRECTIVE 96/82/EC: No components of this mixture are subject to the DIRECTIVE 96/82/EC.

DIRECTIVE 2008/105/EC: No components of this mixture are subject to the DIRECTIVE 2008/105/EC.

REGULATION (EC) No 850/2004: This mixture does not contain any persistent organic pollutants.

REGULATION (EC) No 2037/2000: This mixture does not contain any components that deplete the ozone layer.

Water Hazard Classes: No Water Hazard Classes.

Technical Instructions on Air Quality Control (TA-Luft): This mixture does not contain any hazardous air pollutants.

15.2. Chemical Safety Assessment

Not applicable.

Section 16: Other Information

(viii) Indication of changes

Version	Changes	Date
Version 006	Add a new catalog number; change the national contact; revise the document format according to Regulation (EC) No 1907/2006 (REACH)	March 28, 2019

(ix) Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Dangerous Goods

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air

(x) Key literature references and sources for data

REGULATION (EC) No 1272/2008, Regulation (EC) No 1907/2006 (REACH)

(xi) Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

(xii) Relevant H-statements (number and full text)

Not applicable.

(xiii) Training advice

The employer develop an active training programme of worker protection measures, and consider any measures which may be necessary to protect the environment.

(xiv) Further information

The information provided in this Material 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 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.



SAFETY DATA SHEET *According to Regulation (EC) No 1907/2006 (REACH)*

Product Name	MAGLUMI Wash Concentrate
REF	130299005M

Revision No.: 006

Release Date: March 28 2019



Section 1 Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier:

1.1.1 Mixtures

Designation of the Mixture: MAGLUMI Wash Concentrate

1.1.2 Other means of identification: Not applicable

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

1.2.1 Relevant identified uses: For In Vitro Diagnostic Use

1.2.2 Uses advised against: Not available

1.3 Details of the supplier of the safety data sheet:

Supplier : Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.)

Address : No.16, Jinhui Road, Pingshan New District, 518122, Shenzhen, P.R.China

Telephone : +86-755-21536601

Fax : +86-755-28292740

E-mail : Registration_Dept@snibe.net

National contact : Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Telephone : +49-40-2513175

Fax : +49-40-255726

1.4 Emergency telephone number:

+86-755-21536601

Opening hour: Only available during office hours.

Section 2 Hazards Identification

2.1 Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions of Regulation (EC) 1272/2008.

2.2 Label elements

The product does not require any hazard warnings according to Regulation (EC) 1272/2008.

2.3 Other hazards:Nothing

Section 3 Composition/Information on Ingredients

Substance/Mixture: Mixture

CAS No	EC No	Index No	REACH No	%[weight]	Name
77-86-1	201-064-4	-	-	4.24	TRIS (Tris(Hydroxymethyl)aminomethane)
7647-01-0	231-595-7	-	-	2	Hydrochloric acid

Section 4 First Aid Measures



4.1 Description of first aid measures:

4.1.1 In case of inhalation:

Remove to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Maintain an open airway.

4.1.2 In case of skin contact:

Immediately cleanse the affected skin areas with soap under running water.

4.1.3 In case of eyes contact:

Rinse the affected eye with widely spread lids for 15 minutes under running water whilst protecting the unimpaired eye.

4.1.4 In case of ingestion:

Induce vomiting. If the casualty is still conscious, rinse the mouth and spit the fluids out and drink copious amounts of milk or water. In the meantime call an emergency physician to the scene of the accident.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a doctor/physician.

Section 5 Fire-Fighting Measures

5.1 Extinguishing media: Use water spray, dry chemical, carbon dioxide, or appropriate foam.

5.2 Special hazards arising from the substance or mixture: Not available.

5.3 Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes. During a fire, irritating and toxic gases may be generated by thermal decomposition or combustion.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Wear gloves and respirator to avoid direct contact with the leakage of fluid. Carefully sweep up, gather and remove. Avoid rising dust. Afterwards ventilate area and wash spill site.

6.1.2 For emergency responders:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods for containment and cleaning up: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.



6.4 Reference to other sections: Refer to section 8 and 13 of the SDS.

Section 7 Handling and Storage

7.1 Precautions for safe handling:

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Keep container tightly closed.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Store only in original container. Refer to the package insert or product label for additional information on storage conditions.

Further information on storage conditions: Refer to product label. Protect from heat and direct sunlight.

Advice on common storage: No materials to be especially mentioned.

Other data: No decomposition if stored and applied as directed.

7.3 Specific end use(s): The mixture is intended specifically for in vitro diagnostic use and shall be considered potentially able to transmit infectious agents. Handle in accordance with good laboratory practice (GLP).

Section 8 Exposure Controls/Personal Protection

8.1 Control parameters:

8.1.1 Occupational exposure limits: Not available.

8.1.2 Additional exposure limits under the conditions of use: Not available.

8.1.3 DNEL/DMEL and PNEC-Values: Not available.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.

8.2.2 Personal protective equipment:

8.2.2.1 Eye/face protection: Protective eyeglasses or chemical safety goggles should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

8.2.2.2 Skin protection:

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection: Protective clothing with elasticized cuffs and closed neck. Boots made of PVC.

8.2.2.3 Respiratory protection: Make sure workplace is well ventilated otherwise use a suitable respirator.

8.2.3 Environmental exposure controls: Avoid discharge into the environment. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Section 9 Physical and chemical Properties

9.1 Information on basic physical and chemical properties

Appearance:

Clear or colorless aqueous solution



Colour:	Colorless
Odour:	Not available
Odour threshold:	Not available
pH:	7.2-8.8
Melting point/range (°C):	Not available
Boiling point/range (°C) :	Not available
Decomposition temperature(°C):	Not available
Flash point (°C) :	Not available
Ignition temperature (°C) :	Not available
Vapour pressure (20°C) :	Not available
Vapour density:	Not available
Density(g/cm3):	Not available
Relative density:	Not available
Water solubility (g/l) at 20°C :	Miscible in water
Solubility(ies):	Not available
Partition coefficient	Not available
n-Octanol/Water (log Po/w) :	Not available
Viscosity, dynamic (20 °C) :	Not available

9.2 Physical hazards:

Explosives	Not available
Flammable gases	Not available
Flammable aerosols	Not available
Oxidising gases	Not available
Gases under pressure	Not available
Flammable liquids	Not available
Flammable solids	Not available
Self-reactive substances and mixtures	Not available
Pyrophoric liquids	Not available
Pyrophoric solids	Not available
Self-heating substances and mixtures	Not available
Substances or mixtures which, in contact with water emit flammable gases	Not available
Oxidising liquids	Not available
Oxidising solids	Not available
Organic peroxides	Not available
Metal corrosion	Not available

9.3 Other safety information:

Limiting oxygen concentration	Not available
-------------------------------	---------------



Bulk density	Not available
Solubility in different media	Not available
Stability in organic solvents and identity of relevant degradation products	Not available
Evaporation rate	Not available
Conductivity	Not available
Surface tension	Not available
Dissociation constant in water (pKa)	Not available
Oxidation-reduction Potential	Not available
Fat solubility (solvent – oil to be specified)	Not available

Section 10 Stability and Reactivity

10.1 Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability: Stable under recommended temperatures and pressures.

10.3 Possibility of hazardous reactions: Not available.

10.4 Conditions to avoid: Hygroscopic.

10.5 Incompatible materials: Not available.

10.6 Hazardous decomposition products: In the case of fire, it will break down and produce harmful substances. Carbon oxides, nitrogen oxides

Section 11 Toxicological Information

11.1 Toxic kinetics, metabolism and distribution: Not available.

11.2 Information on toxicological effects:

Acute toxicity:

Hydrochloric acid: Inhalation LC50: 3124 ppm/1H (rat); Oral LD50: 700 mg/kg (rat); Dermal LD50: >5010 mg/kg (rabbit)

Tris: Oral LD50: 5,900 mg/kg (rat)

Skin corrosion/Irritation: Not available

Serious eye damage/irritation: Not available

Respiratory or skin sensitization: Not available

Carcinogenicity: Not available

Germ cell mutagenicity: Not available

Reproductive toxicity: Not available

STOT- single exposure: Not available

STOT-repeated exposure: Not available

Aspiration hazard: Not available

Section 12 Ecological Information



12.1 Toxicity: Not available

12.2 Persistence and degradability: Not available

12.3 Bioaccumulative potential: Not available

12.4 Mobility in soil: Not available.

12.5 Results of PBT&vPvB assessment: This substance does not have persistence, bioaccumulation, and toxicity (PBT).

12.6 Other adverse effects: Not available.

Section 13 Disposal Considerations

13.1 Waste treatment methods: Waste generators must determine whether a discarded contents/container is classified as a hazardous waste. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Contaminated packaging: Please refer to applicable local regulations.

Do not re-use empty containers.

13.1.1 Product / Packaging disposal:

Hazardous waste according to Waste Catalogue Ordinance (AVV): 18 01 06* chemicals consisting of or containing dangerous substances.

13.2 Additional information:

Hazardous waste: The classification of the product may meet the criteria for a hazardous waste.

Section 14 Transport Information

14.1 UN number

ADR/RID:- IMDG:- IATA-DGR:-

14.2 UNproper shipping name

ADR/RID:Not dangerous goods

IMDG: Not dangerous goods

IATA-DGR: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID:- IMDG:- IATA-DGR:-

14.4 Packaging group

ADR/RID:- IMDG:- IATA-DGR:-

14.5 Environmental hazards

ADR/RID:no IMDG:no IATA-DGR:no

14.6 Special precautions for user

Please select the appropriate means of transport and the corresponding transportation and storage conditions according to the chemical properties. Vehicles should be equipped with the appropriate variety and quantity of fire fighting materials



Leakage emergency handling equipment. If you choose road transportation, please follow the prescribed route.

14.7 Incompatible materials

Strong oxidizer

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EC) No 689/2008: No components of this mixture are subject to the REGULATION (EC) No 689/2008.

DIRECTIVE 96/82/EC: No components of this mixture are subject to the DIRECTIVE 96/82/EC.

DIRECTIVE 2008/105/EC: No components of this mixture are subject to the DIRECTIVE 2008/105/EC.

REGULATION (EC) No 850/2004: This mixture does not contain any persistent organic pollutants.

REGULATION (EC) No 2037/2000: This mixture does not contain any components that deplete the ozone layer.

Water Hazard Classes: No Water Hazard Classes.

Technical Instructions on Air Quality Control (TA-Luft): This mixture does not contain any hazardous air pollutants.

15.2 Chemical Safety Assessment: Safety evaluation of chemical substances has not yet been carried out

Section 16 Other Information

(i) Indication of changes

Version	Changes	Date
Version 006	Add a new catalog number; change the national contact; revise the document format according to Regulation (EC) No 1907/2006 (REACH)	March 28, 2019

(ii) Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Dangerous Goods

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air

(iii) Key literature references and sources for data

REGULATION (EC) No 1272/2008, Regulation (EC) No 1907/2006 (REACH)

(iv) Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

(v) Relevant H-statements (number and full text)



Not applicable.

(vi) Training advice

The employer develop an active training programme of worker protection measures, and consider any measures which may be necessary to protect the environment.

(vii) Further information

The information provided in this Material 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 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.



SAFETY DATA SHEET *According to Regulation (EC) No 1907/2006 (REACH)*

Product Name	MAGLUMI System Tubing Cleaning Solution
REF	130299007M

Revision No.: 006

Release Date: March 28 2019

Section 1 Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier:

1.1.1 Mixtures

Designation of the Mixture: MAGLUMI System Tubing Cleaning Solution

1.1.2 Other means of identification:

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

1.2.1 Relevant identified uses: For In Vitro Diagnostic Use

1.2.2 Uses advised against: Not available

1.3 Details of the supplier of the safety data sheet:

Supplier : Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.)

Address : No.16, Jinhui Road, Pingshan New District, 518122, Shenzhen, P.R.China

Telephone : +86-755-21536601

Fax : +86-755-28292740

E-mail : Registration_Dept@snibe.net

National contact : Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Telephone : +49-40-2513175

Fax : +49-40-255726

1.4 Emergency telephone number:

+86-755-21536601

Opening hour: Only available during office hours.

Section 2 Hazards Identification

2.1 Classification of the substance or mixture

Hazard classes/Hazard categories	Hazard statement
Skin irritation, Category 2	H315

2.2 Label elements

Mixtures: System Tubing Cleaning Solution

Hazard pictograms:

Exclamation mark



Warning

Signal Word: Warning.



Hazard Statement: H315: Causes skin irritation.

Precautionary statements: P264: Wash hands thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P362: Take off contaminated clothing.

2.3 Other hazards

Section 3 Composition/Information on Ingredients

Substance/Mixture: Mixture

CAS No	EC No	Index No	REACH No	%[weight]	Name
7681-52-9	231-668-3	017-011-00-1	-	2.5	Sodium hypochlorite

Section 4 First Aid Measures

4.1 Description of first aid measures:

4.1.1 In case of inhalation:

Remove to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Maintain an open airway.

4.1.2 In case of skin contact:

Immediately cleanse the affected skin areas with soap under running water.

4.1.3 In case of eyes contact:

Rinse the affected eye with widely spread lids for 15 minutes under running water whilst protecting the unimpaired eye.

4.1.4 In case of ingestion:

Drink plenty of warm water to induce vomiting. Medical treatment.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a doctor/physician.

Section 5 Fire-Fighting Measures

5.1 Extinguishing media: Fog water, carbon dioxide and sand are used to extinguish fire.

5.2 Special hazards arising from the substance or mixture: Hydrogen chloride gas, Sodium oxides.

5.3 Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes. During a fire, irritating and toxic gases may be generated by thermal decomposition or combustion.

Section 6 Accidental Release Measures



6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel: Wear gloves and respirator to avoid direct contact with the leakage of fluid. Carefully sweep up, gather and remove. Avoid rising dust. Afterwards ventilate area and wash spill site.

6.1.2 For emergency responders:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods for containment and cleaning up: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.4 Reference to other sections: Refer to section 8 of the SDS.

6.5 Additional information: Not available.

Section 7 Handling and Storage

7.1 Precautions for safe handling:

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Keep container tightly closed.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, airy warehouse. Keep away from fire and heat. The temperature should not exceed 30 DEG C. Should be stored separately with alkali, avoid by all means

Mixed storage. The storage area shall be equipped with emergency disposal equipment and suitable storage materials.

7.3 Specific end use(s): The mixture is intended specifically for in vitro diagnostic use and shall be considered potentially able to transmit infectious agents. Handle in accordance with good laboratory practice (GLP).

Section 8 Exposure Controls/Personal Protection

8.1 Control parameters:

8.1.1 Occupational exposure limits: No data available.

8.1.2 Additional exposure limits under the conditions of use: No data available.

8.1.3 DNEL/DMEL and PNEC-Values: No data available.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.

8.2.2 Personal protective equipment:



8.2.2.1 Eye/face protection: Protective eyeglasses or chemical safety goggles should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

8.2.2.2 Skin protection:

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection: Protective clothing with elasticized cuffs and closed neck. Boots made of PVC.

8.2.2.3 Respiratory protection: Make sure workplace is well ventilated otherwise use a suitable respirator.

8.2.3 Environmental exposure controls: Avoid discharge into the environment. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Section 9 Physical and chemical Properties

9.1 Information on basic physical and chemical properties

Appearance:	Liquid
Colour:	Light Yellow
Odour:	Smells like chlorine
Odour threshold:	No data available
pH:	12-13
Melting point/range (°C):	No data available
Boiling point/range (°C) :	102.2(°C)
Decomposition temperature(°C):	No data available
Flash point (°C) :	No data available
Ignition temperature (°C) :	No data available
Vapour pressure (20°C) :	No data available
Vapour density:	No data available
Density(g/cm ³):	No data available
Relative density:	No data available
Water solubility (g/l) at 20°C :	No data available
Solubility(ies):	No data available
Partition coefficient	No data available
n-Octanol/Water (log Po/w) :	No data available
Viscosity, dynamic (20 °C) :	No data available

9.2 Physical hazards:

Explosives	Not available
Flammable gases	Not available
Flammable aerosols	Not available
Oxidising gases	Not available
Gases under pressure	Not available
Flammable liquids	Not available



Flammable solids	Not available
Self-reactive substances and mixtures	Not available
Pyrophoric liquids	Not available
Pyrophoric solids	Not available
Self-heating substances and mixtures	Not available
Substances or mixtures which, in contact with water emit flammable gases	Not available
Oxidising liquids	Not available
Oxidising solids	Not available
Organic peroxides	Not available
Metal corrosion	Not available

9.3 Other safety information:

Limiting oxygen concentration	Not available
Bulk density	Not available
Solubility in different media	Not available
Stability in organic solvents and identity of relevant degradation products	Not available
Evaporation rate	Not available
Conductivity	Not available
Surface tension	Not available
Dissociation constant in water (pKa)	Not available
Oxidation-reduction Potential	Not available
Fat solubility (solvent – oil to be specified)	Not available

Section 10 Stability and Reactivity

10.1 Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability: Stable under recommended temperatures and pressures.

10.3 Possibility of hazardous reactions: No data available.

10.4 Conditions to avoid: Strong acids and bases, Oxidizing agents, Heavy metals.

10.5 Incompatible materials: Strong acids and bases, Oxidizing agents, Heavy metals.

10.6 Hazardous decomposition products:

Hazardous decomposition products may form under fire conditions—Hydrogen chloride gas, Sodium oxides.

Other decomposition products: no data available.

Section 11 Toxicological Information

11.1 Toxic kinetics, metabolism and distribution: No data available.



11.2 Information on toxicological effects:

Acute toxicity: No specific data.

Skin corrosion/Irritation: Causes skin irritation

Serious eye damage/irritation: Causes serious eye damage.

Respiratory or skin sensitization: No specific data.

Carcinogenicity: No known significant effects or critical hazards.

Germ cell mutagenicity: No specific data.

Reproductive toxicity: No specific data.

STOT- single exposure: No specific data.

STOT-repeated exposure: No specific data.

Aspiration hazard: No specific data.

Section 12 Ecological Information

12.1 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.

12.5 Results of PBT&vPvB assessment: No data available.

12.6 Other adverse effects: No data available.

Section 13 Disposal Considerations

13.1 Waste treatment methods: Waste generators must determine whether a discarded contents/container is classified as a hazardous waste. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Contaminated packaging: Please refer to applicable local regulations.

Do not re-use empty containers.

13.1.1 Product / Packaging disposal:

Hazardous waste according to Waste Catalogue Ordinance (AVV): 18 01 06* chemicals consisting of or containing dangerous substances.

13.2 Additional information:

Hazardous waste: The classification of the product may meet the criteria for a hazardous waste.

Section 14 Transport Information

14.1 UN number: 1791

14.2 UN proper shipping name; nothing

14.3 Transport hazard class(es): nothing

14.4 Packing group:Packing mark :20/Packing category :053/Packing method:no data



14.5 Environmental hazards: Hazardous to the environment

14.6 Special precautions for user: Operators must undergo special training and strictly follow the operating procedures

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Not applicable

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EC) No 649/2012: No components of this mixture are subject to the REGULATION (EC) No 689/2008.

DIRECTIVE 96/82/EC: No components of this mixture are subject to the DIRECTIVE 96/82/EC.

DIRECTIVE 2008/105/EC: No components of this mixture are subject to the DIRECTIVE 2008/105/EC.

REGULATION (EC) No 850/2004: This mixture does not contain any persistent organic pollutants.

REGULATION (EC) No 2037/2000: This mixture does not contain any components that deplete the ozone layer.

Water Hazard Classes: No Water Hazard Classes.

Technical Instructions on Air Quality Control (TA-Luft): This mixture does not contain any hazardous air pollutants.

15.2 Chemical Safety Assessment: Not applicable.

Section 16 Other Information

(i) **16.1** Indication of changes

Version	Changes	Date
Version 006	Add a new catalog number; change the national contact; revise the document format according to Regulation (EC) No 1907/2006 (REACH)	March 28, 2019

(ii) Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Dangerous Goods

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air

(iii) Key literature references and sources for data

REGULATION (EC) No 1272/2008, Regulation (EC) No 1907/2006 (REACH)

(iv) Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

(v) Relevant H-statements (number and full text)



Not applicable.

(vi) Training advice

The employer develop an active training programme of worker protection measures, and consider any measures which may be necessary to protect the environment.

(vii) Further information

The information provided in this Material 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 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.



SAFETY DATA SHEET *According to Regulation (EC) No 1907/2006 (REACH)*

AND REGULATION (EU) 2015/830

Product Name	MAGLUMI Light Check
REF	130299006M
Components	BSA-ABEI (containing BSA, N-(4-Aminobutyl)-N-ethylisoluminol)
	Phosphate Buffer (pH7.4)
	Natriumazid

Revision No.: 006

Release Date: 28th Mar, 2019



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

1.1.1. Mixtures

Designation of the Mixture: MAGLUMI Light Check Natriumazid.

1.1.2. Other means of identification: Not applicable

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

1.2.1. Relevant identified uses: For In Vitro Diagnostic Use

1.2.2. Uses advised against: Not available

1.3. Details of the supplier of the safety data sheet

Supplier : Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE Co., Ltd.)
Address : No.16,Jinhui Road, Pingshan New District, 518122,Shenzhen, P.R.China
Telephone : +86-755-21536601
Fax : +86-755-28292740
E-mail : Registration_Dept@snibe.net
National contact : Shanghai International Holding Corp. GmbH (Europe)
Address : Eiffestrasse 80, 20537 Hamburg, Germany
Telephone : +49-40-2513175
Fax : +49-40-255726

1.4. Emergency telephone number

+86-755-21536601

Opening hour: Only available during office hours.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. However a safety data sheet is being supplied for it upon request as it contains a substance for which there is a Union workplace exposure limit.

2.2. Label elements

The product does not require any hazard warnings according to Regulation (EC) 1272/2008.

2.3. Other hazards

Potential biological hazard: contains biological materials of human/animal origin.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substances/Mixtures: Mixtures

Name	%[weight]	CAS No	EC No	Index No	Classification according to Regulation (EC) No 1272/2008(CLP)
Sodium azide	0.09	26628-22-8	247-852-1	011-004-00-7	Acute Tox. 2, H300; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 EUH032

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008

Additional information: For the wording of the listed relevant phrases and hazard statements, refer to section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

4.1.1. In case of inhalation: Remove to fresh air immediately. Artificial respiration if indicated. Refer for medical attention.



- 4.1.2. In case of skin contact: Remove contaminated clothes. Immediately cleanse the affected skin areas with soap under running water.
- 4.1.3. In case of eyes contact: Rinse the affected eye with widely spread lids for 15 minutes under running water whilst protecting the unimpaired eye.
- 4.1.4. In case of ingestion: Rinse mouth. Do NOT induce vomiting. Give one or two glasses of water to drink. Rest. Refer for medical attention.

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.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Use dry chemical, carbon dioxide, or appropriate foam.

Unsuitable extinguishing media: Water

5.2. Special hazards arising from the substance or mixture

Reacts with copper, lead, silver, mercury and carbon disulfide to form particularly shock-sensitive compounds. Reacts with acids, forming toxic and explosive hydrogen azide. Toxic gases, ash, may be generated by thermal decomposition or combustion.

5.3. Advice for firefighters

Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes. During a fire, irritating and toxic gases may be generated by thermal decomposition or combustion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

- 6.1.1. For non-emergency personnel: Wear gloves and respirator to avoid direct contact with the leakage of fluid. Clean the ground and all materials due to pollution of this mixture with 5% sodium hypochlorite solution. Carefully sweep up, gather and remove. Avoid rising dust. Afterwards ventilate area and wash spill site.
- 6.1.2. For emergency responders:
- See Section 7 for information on safe handling.
 - See Section 8 for information on personal protective equipment.
 - See Section 13 for information on disposal.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

- 6.3.1. For containment: Keep in suitable, closed containers for disposal.
- 6.3.2. For cleaning up: Pick up and arrange disposal without creating dust. Carefully collect remainder, then remove to safe place.

6.4. Reference to other sections

Refer to sections 8 and 13 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

- 7.1.1. Protective measures: Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material. Keep tightly closed when not in use. Since emptied containers retain product residue, follow label warnings even after container is emptied. Do not reuse container. Use only with adequate ventilation.



7.1.2. Advice on general occupational hygiene: Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Store only in original container. Refer to the package insert or product label for additional information on storage conditions.

Further information on storage conditions: Refer to product label. Protect from heat and direct sunlight.

Advice on common storage: No materials to be especially mentioned.

Other data: No decomposition if stored and applied as directed.

7.3. Specific end use(s)

The mixture is intended specifically for in vitro diagnostic use and shall be considered potentially able to transmit infectious agents. Handle in accordance with good laboratory practice (GLP), while also considering the risks deriving from the materials under analysis.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

8.1.1. Occupational exposure limit values:

Substance	Sodium azide				Legal basis
CAS Number	26628-22-8				
Country	Limit value-Eight hours		Limit value-Short term		
	ppm	mg/m ³	ppm	mg/m ³	
Austria	-	0.1	-	0.3	Grenzwerte für Arbeitsstoffe und über krebserzeugende Arbeitsstoffe (Grenzwerteverordnung 2007 - GKV 2007)
Belgium	-	0.1	-	0.3	Annex 1 of the Arrêté royal du 11 mars 2002 relatif à la protection de la santé et de la sécurité des travailleurs contre les risques liés à des agents chimiques sur le lieu de travail.
Denmark	-	0.1	-	0.2	Grænseværdier for stoffer og materialer
European Union	-	0.1	-	0.3	COMMISSION DIRECTIVE 2000/39/EC
Finland	-	0.1	-	0.3(1)	Finnish Ministry of Social Affairs and Health
France	-	0.1	-	0.3	Order of 9 February 2006 Decree No. 2006-133
Germany (AGS)	-	0.2	-	0.4(1)	TRGS 900: Occupational exposure limits (Arbeitsplatzgrenzwerte).
Germany (DFG)	-	0.2 inhalable aerosol	-	0.4 inhalable aerosol	TRGS 900: Occupational exposure limits (Arbeitsplatzgrenzwerte).
Hungary	-	0.1	-	0.3	Ordinance No.25/2000, of 30 Sept., concerning the chemical safety of



					workplaces
Ireland	-	0.1	-	0.3(1)	Schedule 1 to the 2002 <i>Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001.</i>
Italy	-	0.1	-	0.3	-
Latvia	-	0.1	-	0.3(1)	-
Poland	-	0.1	-	0.3	Workplace Safety and Health (General Provisions) Regulations 2006
Spain	-	0.1	-	0.3	Límites de exposición profesional para agentes químicos en España (2008)
United Kingdom	-	0.1	-	0.3	Health and Safety Executive (HSE) Guidance Note EH40 Workplace exposure limits
Remarks					
Australia	(1) Ceiling limit value (2) For the two substances marked with this footnote (Benomyl, and Sodium azide), the exposure standards are established as gravimetric (mg/m ³) values and converted into volumetric values.				
European Union	Bold-type: Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure				
Finland	(1) 15 minutes average value				
France	Bold type: Restrictive statutory limit values				
Germany (AGS)	(1) 15 minutes average value				
Germany (DFG)	STV 15 minutes average value				
Ireland	(1) 15 minutes reference period				
Italy	skin				
Latvia	(1) 15 minutes average value				
Spain	skin				

8.1.2. Information on monitoring procedures: Not available.

8.2. Exposure controls

8.2.1. Appropriate engineering controls: Use adequate ventilation to keep airborne concentrations low.

8.2.2. Personal protective equipment:

8.2.2.1. Eye/face protection: Protective eyeglasses or chemical safety goggles should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

8.2.2.2. Skin protection: Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
 Remarks: *The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.*

Body protection: Protective clothing with elasticized cuffs and closed neck. Boots made of PVC.



8.2.2.3. Respiratory protection: Make sure workplace is well ventilated otherwise use a suitable respirator.

8.2.3. Environmental exposure controls: Avoid discharge into the environment. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

(a) Appearance	Liquid
The physical state:	
Colour:	colourless
(b) Odour:	No data available
(c) Odour threshold;	No data available
(d) pH:	No data available
(e) Melting point/freezing point;	No data available
(f) Initial boiling point and boiling range;	No data available
(g) Flash point;	No data available
(h) Evaporation rate;	No data available
(i) Flammability (solid, gas);	No data available
(j) Upper/lower flammability or explosive limits;	No data available
(k) Vapour pressure;	No data available
(l) Vapour density;	No data available
(m) Relative density;	No data available
(n) Solubility(ies);	No data available
(o) Partition coefficient: n-octanol/water;	No data available
(p) Auto-ignition temperature;	No data available
(q) Decomposition temperature;	No data available
(r) Viscosity;	No data available
(s) Explosive properties;	No data available
(t) Oxidising properties.	No data available

9.2. Other information

(a) Limiting oxygen concentration	Not available
Bulk density	Not available
(b) Solubility in different media	No data available
(c) Stability in organic solvents and identity of relevant degradation products	Not available
(d) Evaporation rate	Not available
(e) Conductivity	Not available
(f) Surface tension	Not available
(g) Dissociation constant in water (pKa)	Not available
Oxidation-reduction Potential	Not available
(h) Fat solubility (solvent – oil to be specified)	Not available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Stable under recommended transport or storage conditions.

10.2. Chemical stability

Stable under recommended temperatures and pressures.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid



Incompatible materials, Strong oxidants.

10.5. Incompatible materials

Halogenated hydrocarbon, Metals, Acids, Acid chlorides, Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products formed under fire conditions-- Nitric Oxide, Hydronitric Acid.

Other decomposition products: no data available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity:

	Parameter	Animal species	Data
Mixture(Magnetic Microbeads)	No data available		
Hazardous component (100% Sodium azide)	LD-50 (oral)	rat	27 mg/kg
	LD-50 (dermal)	rabbit	20 mg/kg
	LC-50 4-hour (inhalation)	rat	37 mg/m ³

Skin corrosion/Irritation: No specific data.

Serious eye damage/irritation: No specific data.

Respiratory or skin sensitization: No specific data.

Germ cell mutagenicity: No specific data.

Carcinogenicity: No known significant effects or critical hazards.

Reproductive toxicity: No specific data.

STOT- single exposure: No specific data.

STOT-repeated exposure: No specific data.

Aspiration hazard: No specific data.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

	Parameter	Animal species	Time of exposure	Data
Mixture(Magnetic Microbeads)	No data available			
Hazardous component (100% Sodium azide)	LC-50	Fish (Rainbow trout)	96 hours	0.8-1.6mg/L
	LC-50	Fish (Bluegill)	96 hours	0.8 mg/L
	EC-50	Crustacea (Daphnia pulex)	96 hours	4.2mg/L
	EC-50	Crustacea (Simocephalus)	96 hours	8.4mg/L

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Other adverse effects

No data available.



SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

13.1.1. Product / Packaging disposal:

Waste codes / waste designations: Hazardous waste according to Waste Catalogue Ordinance (AVV): 18 01 06* chemicals consisting of or containing dangerous substances.

13.1.2. Waste treatment-relevant information:

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. The waste material must be burn and incinerated. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

13.1.3. Sewage disposal-relevant information:

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. The liquid waste must be purified by 5% sodium hypochlorite half an hour.

13.1.4. Other disposal recommendations:

Do not re-use empty containers. NO contact with acids, heavy metals.

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

Not applicable. The product is not classified to be a dangerous goods for any mode of transport, according to *UN Model Regulations ADR, RID, AND, IMDG, ICAO*.

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class (es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EU) No 649/2012: No components of this mixture are subject to the REGULATION (EU) No 649/2012.

DIRECTIVE 96/82/EC: No components of this mixture are subject to the DIRECTIVE 96/82/EC.

DIRECTIVE 2008/105/EC: No components of this mixture are subject to the DIRECTIVE 2008/105/EC.

REGULATION (EC) No 850/2004: This mixture does not contain any persistent organic pollutants.

REGULATION (EC) No 2037/2000: This mixture does not contain any components that deplete the ozone layer.

National regulations (Germany):

Water Hazard Classes: No Water Hazard Classes.

Technical Instructions on Air Quality Control (TA-Luft): This mixture does not contain any hazardous air pollutants.

15.2. Chemical Safety Assessment

Not applicable.

SECTION 16: OTHER INFORMATION

16.1. Indication of changes

Version	Revision Date	Release Date
---------	---------------	--------------

006	According to the new safety regulation to evaluate the material safety	28th Mar,2019
-----	--	---------------

16.2. Abbreviations and acronyms

<i>Acute toxicity</i>	<i>Hazardous to the aquatic environment</i>
<i>GHS06</i>	<i>GHS09</i>
	

Relevant phrases:

According to regulations (EC) 1272/2008 (CLP)

Acute toxicity (Category 2)

Acute aquatic toxicity (Category 1)

Chronic aquatic toxicity (Category 1)

Hazard statements:

H300 Acute toxicity (oral)

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Dangerous Goods

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air

LC-50: Lethal concentration, 50 percent

EC-50: Effective concentration, 50 percent

16.3. Key literature references and sources for data

- (1) Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 2947.
- (2) U.S. Department of Interior, Fish and Wildlife Service. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. Resource Publication No. 137. Washington, DC: U.S. Government Printing Office, 1980., p. 12.
- (3) NIOSH. International Chemical Safety Cards (ICSC). <http://www.cdc.gov/niosh/ipcsneng/neng0950.html>
- (4) GESTIS - International limit values for chemical agents (Occupational exposure limits, OELs). <http://www.dguv.de/ifa/GESTIS/GESTIS-Internationale-Grenzwerte-f%C3%BCr-chemische-Substanzen-limit-values-for-chemical-agents/index-2.jsp>
- (5) TOXNET. <https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~TWLxqx:1:animal>

16.4. Other information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP].

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) 1272/2008 [CLP], based on Calculation method.

16.5. Relevant H-statements (number and full text)

Not applicable.

16.6. Training advice

The employer shall develop an active training programme of worker protection measures, which is specific to the individual workplace, and consider any measures which may be necessary to protect the environment.

16.7. Further information



Shenzhen New Industries Biomedical
Engineering Co., Ltd.

SAFETY DATA SHEET

SJ-SDS-EU-314

V 006 Date: 28th Mar, 2019

The information provided in this Material 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 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.