

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

1.1. Product identifier

Product Name : bioelisa CHAGAS

Product code : 3000-1236

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

Not additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.

Can Malé s/n

08186 Lliçà d'Amunt – Spain

T +34-93 8609000 – F +34-93 8609017

infosds@biokit.com – www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2. Composition/information on components

P/N	Component name	Component classification according to Regulation (EC) no. 1272/2008 [CLP]	Kit Configuration
3200-2562	Microplate	Not classified	1 unit
3200-2563	Concentrate Conjugate	Not classified	1 x 0.35 mL
3200-2603	Conjugate Diluent	Not classified	1 x 15 mL
3200-2564	Positive Control	Not classified	1 x 2.0 mL
3200-2565	Negative Control	Not classified	1 x 3.0 mL
3200-3439	Sample Diluent	Not classified	1 x 30 mL
3200-2737	Concentrate Washing Solution	Not classified	2 x 50 mL
3200-2738	Substrate Buffer	Not classified	1 x 14 mL
3200-2739	Chromogen	Not classified	1 x 1.5 mL
3200-2740	Stopping Solution	Danger – H314, H318	1 x 12 mL

SECTION 3. Disclaimer

This document is intended only as a guide to appropriate precautionary handling of this product by a trained person, or supervised by a person trained in chemical handling. The product shall not be used for purposes different from those indicated in section 1, unless having received suitable written instructions on how to handle the material. Use the product in accordance with the Good Laboratory Practice. This document cannot describe all potential dangers of use or interaction with other chemicals or materials. It is the user's responsibility for the product's safe use, the product's suitability for the intended use and the product's safe disposal. No representation or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made hereunder with respect to the information set forth herein or to the product to which the information refers. The contained information in this SDS are in accordance with Annex II of the COMMISSION REGULATION (EU) No 2015/830 of 01 June 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, authorization and Restriction of Chemicals (REACH), and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

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

1.1. Product identifier

Product name : Microplate
Product code : 3200-2562
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
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1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow breathing of fresh air. Allow the victim to rest.

Microplate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.
Explosion hazard : Product is not explosive.
Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight.
Storage temperature : 2 - 8 °C
Heat and ignition sources : conditions to be avoided.
Prohibitions on mixed storage : Heat sources. Direct sunlight.
Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

Microplate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure.
Materials for protective clothing	: Wear suitable protective clothing
Hand protection	: Wear protective gloves
Eye protection	: Chemical goggles or safety glasses
Respiratory protection	: Respiratory protection equipment not absolutely necessary



Environmental exposure controls	: Avoid release to the environment.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Colourless.
Odour	: Odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

Microplate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Microplate

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

Microplate

Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Microplate

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			

Microplate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

ADR	IMDG	IATA	RID
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Microplate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Concentrate Conjugate
Product code : 3200-2563
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
Extra phrases : 50% of the mixture consist of ingredient(s) of unknown toxicity for human health and aquatic environment.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
Other hazards not contributing to the classification : The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious. The product contains rabbit material. All donor animals come from farms free of the disease. The cattle received ante- and post mortem health by a vet and having absence of infectious and contagious material. However, the material should be treated as potentially infectious.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Concentrate Conjugate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Thimerosal	(CAS No) 54-64-8 (EC no) 200-210-4 (EC index no) 080-004-00-7	< 0,1	T+; R26/27/28 N; R50/53 R33	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 1 (Inhalation), H330 STOT RE 2, H373 Aquatic Chronic 1, H410
Gentamicin sulphate	(CAS No) 1405-41-0 (EC no) 215-778-9	< 0,1	R42 R43	Resp. Sens. 1, H334 Skin Sens. 1, H317

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Allow breathing of fresh air. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Not flammable.
- Explosion hazard : Product is not explosive.
- Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

Concentrate Conjugate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 2 - 8 °C

Heat and ignition sources : conditions to be avoided.

Prohibitions on mixed storage : Heat sources. Direct sunlight.

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Materials for protective clothing : Wear suitable protective clothing

Hand protection : Wear protective gloves

Eye protection : Chemical goggles or safety glasses

Respiratory protection : Respiratory protection equipment not absolutely necessary



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Dark red.

Odour : Odourless.

Odour threshold : No data available

pH : ≈ 7,6 (7,55 - 7,65)

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : Non flammable

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : No data available

Density : 1,011 g/ml

Solubility : Completely soluble.

Log Pow : No data available

Concentrate Conjugate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Thimerosal (54-64-8)	
LD50 oral rat	75 mg/kg
LD50 dermal	98 mg/kg

Gentamicin sulphate (1405-41-0)	
LD50 oral rat	> 5000 mg/kg

Skin corrosion/irritation	: Not classified
	Based on available data, the classification criteria are not met pH: ≈ 7,6 (7,55 - 7,65)
Serious eye damage/irritation	: Not classified
	Based on available data, the classification criteria are not met pH: ≈ 7,6 (7,55 - 7,65)
Respiratory or skin sensitisation	: Not classified
	Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
	Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
	Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
	Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified
	Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified
	Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
	Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Concentrate Conjugate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Thimerosal (54-64-8)	
LC50 fish 1	21 mg/l (48h) <i>Lepomis macrochirus</i>
LC50 fish 2	64,5 mg/l (48h) <i>Oncorhynchus mykiss</i>

12.2. Persistence and degradability

Concentrate Conjugate	
Persistence and degradability	Not established.

Thimerosal (54-64-8)	
Persistence and degradability	May cause long-term adverse effects in the environment.

Gentamicin sulphate (1405-41-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Concentrate Conjugate	
Bioaccumulative potential	Not established.

Thimerosal (54-64-8)	
Bioaccumulative potential	Not established.

Gentamicin sulphate (1405-41-0)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Concentrate Conjugate	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

Concentrate Conjugate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Recommendations Danish Regulation : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Inhalation)	Acute toxicity (inhal.), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Resp. Sens. 1	Sensitisation — Respiratory, category 1
Skin Sens. 1	Sensitisation — Skin, category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H310	Fatal in contact with skin
H317	May cause an allergic skin reaction
H330	Fatal if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H373	May cause damage to organs through prolonged or repeated exposure
H410	Very toxic to aquatic life with long lasting effects

Concentrate Conjugate

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Conjugate Diluent
Product code : 3200-2603
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
Extra phrases : 50% of the mixture consist of ingredient(s) of unknown toxicity for human health and aquatic environment.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
Other hazards not contributing to the classification : The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

Conjugate Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.
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6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage temperature	: 2 - 8 °C
Heat and ignition sources	: conditions to be avoided.
Prohibitions on mixed storage	: Heat sources. Direct sunlight.
Special rules on packaging	: Keep only in original container.

Conjugate Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure.
Materials for protective clothing	: Wear suitable protective clothing
Hand protection	: Wear protective gloves
Eye protection	: Chemical goggles or safety glasses
Respiratory protection	: Respiratory protection equipment not absolutely necessary



Environmental exposure controls	: Avoid release to the environment.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Yellow.
Odour	: Odourless.
Odour threshold	: No data available
pH	: ≈ 7,6 (7,55 - 7,65)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,051 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

Conjugate Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: $\approx 7,6$ (7,55 - 7,65)
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: $\approx 7,6$ (7,55 - 7,65)
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Conjugate Diluent

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

Conjugate Diluent

Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Conjugate Diluent

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Additional information : Avoid release to the environment

Conjugate Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

Conjugate Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

NIET-limitatieve lijst van voor de voortplanting : None of the components are listed

giftige stoffen – Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting : None of the components are listed

giftige stoffen – Ontwikkeling

Denmark

Recommendations Danish Regulation

: Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information

: None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Positive Control
Product code : 3200-2564
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
Extra phrases : 25% of the mixture consists of ingredients of unknown toxicity for human health and aquatic environment.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
Other hazards not contributing to the classification : This product contains human source material that tested non-reactive for HIV 1+2 antibodies, Hepatitis B Surface Antigen and Hepatitis C virus antibodies. Tested using FDA approved tests. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious. The product contains goat material. All donor animals come from farms free of the disease. The cattle received ante- and post mortem health by a vet and having absence of infectious and contagious material. However, the material should be treated as potentially infectious.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Positive Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Triton X-100 substance listed as REACH Candidate 4- (1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]	(CAS No) 9002-93-1	0,75 - 1	Xn; R22 Xi; R36 N; R51/53	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 2, H411
sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Allow breathing of fresh air. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Not flammable.
- Explosion hazard : Product is not explosive.
- Hazardous decomposition products in case of fire : Carbon oxydes (CO, CO₂). Nitrogen oxides (NO_x) and sulphur oxides.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

Positive Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 2 - 8 °C

Heat and ignition sources : conditions to be avoided.

Prohibitions on mixed storage : Heat sources. Direct sunlight.

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

sodium azide (26628-22-8)		
EU	Local name	Sodium azide
EU	IOELV TWA (mg/m ³)	0,1 mg/m ³
EU	IOELV STEL (mg/m ³)	0,3 mg/m ³
EU	Notes	Skin
France	Local name	Azide de sodium
France	VME (mg/m ³)	0,1 mg/m ³
France	VLE (mg/m ³)	0,3 mg/m ³
Germany	Local name	Natriumazid
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,2 mg/m ³
Germany	Remark (TRGS 900)	DFG,EU
Italy	Local name	Azoturo di sodio
Italy	OEL TWA (mg/m ³)	0,1 mg/m ³
Italy	OEL STEL (mg/m ³)	0,3 mg/m ³
Portugal	Local name	Azida de sódio como Azida de sódio como vapor de Ácido hidroazóico
Portugal	OEL - Ceilings (mg/m ³)	0,29 mg/m ³
Portugal	OEL - Ceilings (ppm)	0,11 ppm

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Materials for protective clothing : Wear suitable protective clothing

Hand protection : Wear protective gloves

Eye protection : Chemical goggles or safety glasses

Respiratory protection : Respiratory protection equipment not absolutely necessary



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Green.

Odour : Odourless.

Positive Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Odour threshold	: No data available
pH	: $\approx 7,5$ (7,45 - 7,55)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,049 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rat	50 mg/kg
LD50 dermal rabbit	20 mg/kg
Triton X-100 (9002-93-1)	
LD50 oral rat	1800 mg/kg
LD50 dermal rabbit	8000 mg/kg

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met
pH: $\approx 7,5$ (7,45 - 7,55)

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met
pH: $\approx 7,5$ (7,45 - 7,55)

Respiratory or skin sensitisation : Not classified

Based on available data, the classification criteria are not met

Positive Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2 mg/l (96 h)
Triton X-100 (9002-93-1)	
LC50 fish 1	8,9 mg/l (96h)
EC50 Daphnia 1	26 mg/l (48h)

12.2. Persistence and degradability

Positive Control	
Persistence and degradability	Not established.
Triton X-100 (9002-93-1)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Positive Control	
Bioaccumulative potential	Not established.
Triton X-100 (9002-93-1)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Component	
Triton X-100 (9002-93-1)	PBT: not yet assessed vPvB: not yet assessed

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable

Positive Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

ADR	IMDG	IATA	RID
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: Triton X-100 (CAS 9002-93-1)

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
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Positive Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H300	Fatal if swallowed
H302	Harmful if swallowed
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Negative Control
Product code : 3200-2565
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
EUH-statements : EUH210 - Safety data sheet available on request
Extra phrases : 20% of the mixture consists of ingredients of unknown toxicity for human health and aquatic environment.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
Other hazards not contributing to the classification : This product contains human source material that tested non-reactive for HIV 1+2 antibodies, Hepatitis B Surface Antigen and Hepatitis C virus antibodies. Tested using FDA approved tests. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease. The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious. The product contains goat material. All donor animals come from farms free of the disease. The cattle received ante- and post mortem health by a vet and having absence of infectious and contagious material. However, the material should be treated as potentially infectious.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Negative Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Triton X-100 substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues])	(CAS No) 9002-93-1	1 - 2	Xn; R22 Xi; R36 N; R51/53	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 2, H411
sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.
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6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

Negative Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 2 - 8 °C

Heat and ignition sources : conditions to be avoided.

Prohibitions on mixed storage : Heat sources. Direct sunlight.

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

sodium azide (26628-22-8)		
EU	Local name	Sodium azide
EU	IOELV TWA (mg/m ³)	0,1 mg/m ³
EU	IOELV STEL (mg/m ³)	0,3 mg/m ³
EU	Notes	Skin
France	Local name	Azide de sodium
France	VME (mg/m ³)	0,1 mg/m ³
France	VLE (mg/m ³)	0,3 mg/m ³
Germany	Local name	Natriumazid
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,2 mg/m ³
Germany	Remark (TRGS 900)	DFG,EU
Italy	Local name	Azoturo di sodio
Italy	OEL TWA (mg/m ³)	0,1 mg/m ³
Italy	OEL STEL (mg/m ³)	0,3 mg/m ³
Portugal	Local name	Azida de sódio como Azida de sódio como vapor de Ácido hidroazóico
Portugal	OEL - Ceilings (mg/m ³)	0,29 mg/m ³
Portugal	OEL - Ceilings (ppm)	0,11 ppm

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Materials for protective clothing : Wear suitable protective clothing

Hand protection : Wear protective gloves

Eye protection : Chemical goggles or safety glasses

Respiratory protection : Respiratory protection equipment not absolutely necessary



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Yellow.

Odour : Odourless.

Negative Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Odour threshold	: No data available
pH	: ≈ 7,5 (7,45 - 7,55)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,05 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rat	50 mg/kg
LD50 dermal rabbit	20 mg/kg
Triton X-100 (9002-93-1)	
LD50 oral rat	1800 mg/kg
LD50 dermal rabbit	8000 mg/kg

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met
pH: ≈ 7,5 (7,45 - 7,55)

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met
pH: ≈ 7,5 (7,45 - 7,55)

Respiratory or skin sensitisation : Not classified

Based on available data, the classification criteria are not met

Negative Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2 mg/l (96 h)
Triton X-100 (9002-93-1)	
LC50 fish 1	8,9 mg/l (96h)
EC50 Daphnia 1	26 mg/l (48h)

12.2. Persistence and degradability

Negative Control	
Persistence and degradability	Not established.
Triton X-100 (9002-93-1)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Negative Control	
Bioaccumulative potential	Not established.
Triton X-100 (9002-93-1)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Component	
Triton X-100 (9002-93-1)	PBT: not yet assessed vPvB: not yet assessed

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable

Negative Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

ADR	IMDG	IATA	RID
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: Triton X-100 (CAS 9002-93-1)

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
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Negative Control

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H300	Fatal if swallowed
H302	Harmful if swallowed
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
EUH210	Safety data sheet available on request

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Sample Diluent
Product code : 3200-3439
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
EUH-statements : EUH210 - Safety data sheet available on request
Extra phrases : 18.5% of the mixture consists of ingredients of unknown toxicity for human health and aquatic environment.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.
Other hazards not contributing to the classification : The product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious. The product contains goat material. All donor animals come from farms free of the disease. The cattle received ante- and post mortem health by a vet and having absence of infectious and contagious material. However, the material should be treated as potentially infectious.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Sample Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ethanediol, ethylene glycol	(CAS No) 107-21-1 (EC no) 203-473-3 (EC index no) 603-027-00-1 (REACH-no) 01-2119456816-28	7 - 10	Xn; R22	Acute Tox. 4 (Oral), H302
Triton X-100 substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues])	(CAS No) 9002-93-1	0,75 - 1	Xn; R22 Xi; R36 N; R51/53	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 2, H411
sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	T+; R28 R32 N; R50/53	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxydes (CO, CO ₂). Nitrogen oxydes (NO _x) and sulphur oxydes.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.
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Sample Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 2 - 8 °C

Heat and ignition sources : conditions to be avoided.

Prohibitions on mixed storage : Heat sources. Direct sunlight.

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

sodium azide (26628-22-8)		
EU	Local name	Sodium azide
EU	IOELV TWA (mg/m ³)	0,1 mg/m ³
EU	IOELV STEL (mg/m ³)	0,3 mg/m ³
EU	Notes	Skin
France	Local name	Azide de sodium
France	VME (mg/m ³)	0,1 mg/m ³
France	VLE (mg/m ³)	0,3 mg/m ³
Germany	Local name	Natriumazid
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,2 mg/m ³
Germany	Remark (TRGS 900)	DFG,EU
Italy	Local name	Azoturo di sodio
Italy	OEL TWA (mg/m ³)	0,1 mg/m ³
Italy	OEL STEL (mg/m ³)	0,3 mg/m ³
Portugal	Local name	Azida de sódio como Azida de sódio como vapor de Ácido hidroazóico
Portugal	OEL - Ceilings (mg/m ³)	0,29 mg/m ³
Portugal	OEL - Ceilings (ppm)	0,11 ppm

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Materials for protective clothing : Wear suitable protective clothing

Hand protection : Wear protective gloves

Eye protection : Chemical goggles or safety glasses

Respiratory protection : Respiratory protection equipment not absolutely necessary



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Sample Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Colour	: Yellowish.
Odour	: Odourless.
Odour threshold	: No data available
pH	: $\approx 7,45$ (7,2 - 7,7)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,056 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rat	50 mg/kg
LD50 dermal rabbit	20 mg/kg
Triton X-100 (9002-93-1)	
LD50 oral rat	1800 mg/kg
LD50 dermal rabbit	8000 mg/kg
ethanediol, ethylene glycol (107-21-1)	
LD50 oral rat	4700 mg/kg
LD50 dermal rabbit	10626 mg/kg

Sample Diluent

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: ≈ 7,45 (7,2 - 7,7)
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: ≈ 7,45 (7,2 - 7,7)
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2 mg/l (96 h)
Triton X-100 (9002-93-1)	
LC50 fish 1	8,9 mg/l (96h)
EC50 Daphnia 1	26 mg/l (48h)
ethanediol, ethylene glycol (107-21-1)	
LC50 fish 1	18500 mg/l (96h) Oncorhynchus mykiss
EC50 Daphnia 1	74000 mg/l (24h)
LC50 fish 2	> 10000 mg/l (48h) - Leuciscus idus
NOEC chronic fish	39140 mg/l (96 h) - Pimephales promelas

12.2. Persistence and degradability

Sample Diluent	
Persistence and degradability	Not established.
Triton X-100 (9002-93-1)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Sample Diluent	
Bioaccumulative potential	Not established.
Triton X-100 (9002-93-1)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Sample Diluent	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	
Component	
Triton X-100 (9002-93-1)	PBT: not yet assessed vPvB: not yet assessed

Sample Diluent

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12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: Triton X-100 (CAS 9002-93-1)

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

Sample Diluent

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NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H300	Fatal if swallowed
H302	Harmful if swallowed
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
EUH210	Safety data sheet available on request

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Concentrate Washing Solution
Product code : 3200-2737
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Thimerosal	(CAS No) 54-64-8 (EC no) 200-210-4 (EC index no) 080-004-00-7	< 0,1	T+; R26/27/28 N; R50/53 R33	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 1 (Inhalation), H330 STOT RE 2, H373 Aquatic Chronic 1, H410

Full text of R- and H-statements: see section 16

Concentrate Washing Solution

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.
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6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
-------------------------------	--

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage temperature	: 2 - 8 °C
Heat and ignition sources	: conditions to be avoided.
Prohibitions on mixed storage	: Heat sources. Direct sunlight.
Special rules on packaging	: Keep only in original container.

Concentrate Washing Solution

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according to Regulation (EU) No. 2015/830

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure.
Materials for protective clothing	: Wear suitable protective clothing
Hand protection	: Wear protective gloves
Eye protection	: Chemical goggles or safety glasses
Respiratory protection	: Respiratory protection equipment not absolutely necessary



Environmental exposure controls	: Avoid release to the environment.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: Odourless.
Odour threshold	: No data available
pH	: $\approx 7,3$ (7,2 - 7,4)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,02 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

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10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Thimerosal (54-64-8)	
LD50 oral rat	75 mg/kg
LD50 dermal	98 mg/kg
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: ≈ 7,3 (7,2 - 7,4)
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: ≈ 7,3 (7,2 - 7,4)
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Thimerosal (54-64-8)	
LC50 fish 1	21 mg/l (48h) <i>Lepomis macrochirus</i>
LC50 fish 2	64,5 mg/l (48h) <i>Oncorhynchus mykiss</i>

12.2. Persistence and degradability

Concentrate Washing Solution	
Persistence and degradability	Not established.
Thimerosal (54-64-8)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Concentrate Washing Solution	
Bioaccumulative potential	Not established.
Thimerosal (54-64-8)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

Concentrate Washing Solution

Safety Data Sheet

according to Regulation (EU) No. 2015/830

12.5. Results of PBT and vPvB assessment

Concentrate Washing Solution

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

Concentrate Washing Solution

Safety Data Sheet

according to Regulation (EU) No. 2015/830

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Recommendations Danish Regulation : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 1 (Inhalation)	Acute toxicity (inhal.), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H373	May cause damage to organs through prolonged or repeated exposure
H410	Very toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Substrate Buffer
Product code : 3200-2738
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
hydrogen peroxide solution ... %	(CAS No) 7722-84-1 (EC no) 231-765-0 (EC index no) 008-003-00-9	< 0,1	R5 O; R8 C; R35 Xn; R20/22	Ox. Liq. 1, H271 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314

Substrate Buffer

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Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Gentamicin sulphate	(CAS No) 1405-41-0 (EC no) 215-778-9	< 0,1	R42 R43	Resp. Sens. 1, H334 Skin Sens. 1, H317
Sodium salicylate	(CAS No) 54-21-7 (EC no) 200-198-0	< 0,1	Xn; R22 Xi; R36	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319

Specific concentration limits:

Name	Product identifier	Specific concentration limits: DSD/DPD	Specific concentration limits: CLP
hydrogen peroxide solution ... %	(CAS No) 7722-84-1 (EC no) 231-765-0 (EC index no) 008-003-00-9	(5 =< C < 8) Xi;R36 (C >= 8) Xn;R22 (8 =< C < 50) Xi;R41 (35 =< C < 50) Xi;R37/38 (C >= 50) Xn;R20 (50 =< C < 70) C;R34 (C >= 50) O;R8 (C >= 70) C;R35 (C >= 70) R5	(5 =< C < 8) Eye Irrit. 2, H319 (8 =< C < 50) Eye Dam. 1, H318 (35 =< C < 50) Skin Irrit. 2, H315 (C >= 35) STOT SE 3, H335 (50 =< C < 70) Ox. Liq. 2, H272 (50 =< C < 70) Skin Corr. 1B, H314 (C >= 70) Ox. Liq. 1, H271 (C >= 70) Skin Corr. 1A, H314

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxydes (CO, CO ₂). Nitrogen oxydes (NO _x) and sulphur oxydes.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
----------------------	-----------------------------------

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

Substrate Buffer

Safety Data Sheet

according to Regulation (EU) No. 2015/830

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 2 - 8 °C

Heat and ignition sources : conditions to be avoided.

Prohibitions on mixed storage : Heat sources. Direct sunlight.

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

hydrogen peroxide solution ... % (7722-84-1)		
France	Local name	Peroxyde d'hydrogène
France	VME (mg/m ³)	1,5 mg/m ³
France	VME (ppm)	1 ppm
Portugal	Local name	Peróxido de hidrogénio
Portugal	OEL TWA (ppm)	1 ppm
Spain	Local name	Peróxido de hidrógeno
Spain	VLA-ED (mg/m ³)	1,4 mg/m ³
Spain	VLA-ED (ppm)	1 ppm

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Materials for protective clothing : Wear suitable protective clothing

Hand protection : Wear protective gloves

Eye protection : Chemical goggles or safety glasses

Respiratory protection : Respiratory protection equipment not absolutely necessary



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Colourless.

Odour : Odourless.

Odour threshold : No data available

pH : ≈ 6 (5,9 - 6,1)

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Substrate Buffer

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,003 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Gentamicin sulphate (1405-41-0)	
LD50 oral rat	> 5000 mg/kg
Sodium salicylate (54-21-7)	
LD50 oral rat	930 mg/kg
LD50 dermal rabbit	1700 mg/kg
LD50 dermal	550 mg/kg
hydrogen peroxide solution ... % (7722-84-1)	
LD50 oral rat	1193 mg/kg
LD50 dermal rat	> 2000 mg/kg

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: ≈ 6 (5,9 - 6,1)
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: ≈ 6 (5,9 - 6,1)
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met

Substrate Buffer

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Sodium salicylate (54-21-7)	
LC50 fish 1	1370 mg/l Pimephales promelas (96h)
hydrogen peroxide solution ... % (7722-84-1)	
LC50 fish 1	16,4 mg/l Pimephales promelas (96h)
EC50 Daphnia 1	4,2 mg/l (24h)
LOEC (chronic)	1,25 mg/l
NOEC chronic crustacea	0,63 mg/l

12.2. Persistence and degradability

Substrate Buffer	
Persistence and degradability	Not established.
Gentamicin sulphate (1405-41-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Substrate Buffer	
Bioaccumulative potential	Not established.
Gentamicin sulphate (1405-41-0)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Substrate Buffer	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable

Substrate Buffer

Safety Data Sheet

according to Regulation (EU) No. 2015/830

ADR	IMDG	IATA	RID
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
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Substrate Buffer

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Ox. Liq. 1	Oxidising Liquids, Category 1
Resp. Sens. 1	Sensitisation — Respiratory, category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Sens. 1	Sensitisation — Skin, category 1
H271	May cause fire or explosion; strong oxidiser
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H332	Harmful if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Chromogen
Product code : 3200-2739
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation : Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

Chromogen

Safety Data Sheet

according to Regulation (EU) No. 2015/830

First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.
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6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage temperature	: 2 - 8 °C
Heat and ignition sources	: conditions to be avoided.
Prohibitions on mixed storage	: Heat sources. Direct sunlight.
Special rules on packaging	: Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

Chromogen

Safety Data Sheet

according to Regulation (EU) No. 2015/830

8.2. Exposure controls

Personal protective equipment	: Avoid all unnecessary exposure.
Materials for protective clothing	: Wear suitable protective clothing
Hand protection	: Wear protective gloves
Eye protection	: Chemical goggles or safety glasses
Respiratory protection	: Respiratory protection equipment not absolutely necessary



Environmental exposure controls	: Avoid release to the environment.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: Odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,1 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

Chromogen

Safety Data Sheet

according to Regulation (EU) No. 2015/830

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Dimethylsulfoxide (67-68-5)	
LD50 oral rat	14500 mg/kg
LD50 dermal rabbit	> 5000 mg/kg
LC50 inhalation rat (Vapours - mg/l/4h)	40250 mg/l/4h

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified
Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Dimethylsulfoxide (67-68-5)	
LC50 fish 1	34000 mg/l
EC50 Daphnia 1	27500 mg/l

12.2. Persistence and degradability

Chromogen	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Chromogen	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

Chromogen

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
Not regulated for transport			
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Rail transport

Carriage prohibited (RID) : No

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 2, hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Immission Control Act - 12.BImSchV

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

Chromogen

Safety Data Sheet

according to Regulation (EU) No. 2015/830

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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

1.1. Product identifier

Product name : Stopping Solution
Product code : 3200-2740
Type of product : Medical device

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : For In Vitro Diagnostic use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

BIOKIT, S.A.
Can Malé s/n
08186 Lliçà d'Amunt - Spain
T +34-93 8609000 - F +34-93 8609017
infosds@biokit.com - www.biokit.com

1.4. Emergency telephone number

Emergency number : +44 (0) 3700 492 795 +1 215 207 0061 (USA & Canada)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Corr. 1A H314
Eye Dam. 1 H318

Full text of H-statements: see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

C; R35

Full text of R-phrases: see section 16

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS05

Signal word (CLP) : Danger
Hazard statements (CLP) : H314 - Causes severe skin burns and eye damage
Precautionary statements (CLP) : P260 - Do not breathe spray, gas, fume, dust, mist, vapours
P264 - Wash hands thoroughly after handling
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
P280 - Wear eye protection, protective gloves, protective clothing
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

Stopping Solution

Safety Data Sheet

according to Regulation (EU) No. 2015/830

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
sulphuric acid ... %	(CAS No) 7664-93-9 (EC no) 231-639-5 (EC index no) 016-020-00-8	3 - 5	C; R35	Skin Corr. 1A, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits: DSD/DPD	Specific concentration limits: CLP
sulphuric acid ... %	(CAS No) 7664-93-9 (EC no) 231-639-5 (EC index no) 016-020-00-8	(5 =< C < 15) Xi;R36/38 (C >= 15) C;R35	(5 =< C < 15) Skin Irrit. 2, H315 (5 =< C < 15) Eye Irrit. 2, H319 (C >= 15) Skin Corr. 1A, H314

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after skin contact	: Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

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

Symptoms/injuries	: Causes severe skin burns and eye damage.
Symptoms/injuries after eye contact	: Causes serious eye damage.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). Nitrogen oxides (NO _x) and sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

Stopping Solution

Safety Data Sheet

according to Regulation (EU) No. 2015/830

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact during pregnancy/while nursing.

Hygiene measures : Wash ... thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Keep container closed when not in use. Keep only in original container. Keep cool. Protect from sunlight.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 2 - 8 °C

Heat and ignition sources : conditions to be avoided.

Prohibitions on mixed storage : Heat sources. Direct sunlight.

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

This device is intended for In Vitro Diagnostic use. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Materials for protective clothing : Wear suitable protective clothing

Hand protection : Wear protective gloves

Eye protection : Chemical goggles or face shield

Skin and body protection : Wear suitable protective clothing

Respiratory protection : Respiratory protection equipment not absolutely necessary



Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Colourless.

Odour : Odourless.

Odour threshold : No data available

pH : < 1

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Stopping Solution

Safety Data Sheet

according to Regulation (EU) No. 2015/830

Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,03 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Corrosive vapours. Product is not explosive.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Thermal decomposition generates : Corrosive vapours. Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Causes severe skin burns and eye damage. pH: < 1
Serious eye damage/irritation	: Causes serious eye damage. pH: < 1
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met

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Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

Stopping Solution	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Stopping Solution	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Stopping Solution	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations





13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to ...

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	RID
14.1. UN number			
2796	2796	2796	2796
14.2. UN proper shipping name			
SULPHURIC ACID	SULPHURIC ACID	Sulphuric acid	SULPHURIC ACID
Transport document description			
UN 2796 SULPHURIC ACID (sulphuric acid ... (7664-93-9)), 8, II, (E)	UN 2796 SULPHURIC ACID, 8, II		
14.3. Transport hazard class(es)			
8	8	8	8
			
14.4. Packing group			
II	II	II	II
14.5. Environmental hazards			
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available			

14.6. Special precautions for user

- Overland transport

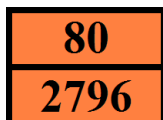
Classification code (ADR) : C1
Limited quantities (ADR) : 11
Excepted quantities (ADR) : E2
Packing instructions (ADR) : P001, IBC02

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Mixed packing provisions (ADR)	: MP15
Portable tank and bulk container instructions (ADR)	: T8
Portable tank and bulk container special provisions (ADR)	: TP2
Tank code (ADR)	: L4BN
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Hazard identification number (Kemler No.)	: 80
Orange plates	:



Tunnel restriction code (ADR)	: E
EAC code	: 2R

- Transport by sea

Limited quantities (IMDG)	: 1 L
Excepted quantities (IMDG)	: E2
Packing instructions (IMDG)	: P001
IBC packing instructions (IMDG)	: IBC02
IBC special provisions (IMDG)	: B20
Tank instructions (IMDG)	: T8
Tank special provisions (IMDG)	: TP2
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-B
Stowage category (IMDG)	: B
Properties and observations (IMDG)	: Colourless liquid, mixture not exceeding 1.405 relative density. Highly corrosive to most metals. Causes burns to skin, eyes and mucous membranes.

- Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y840
PCA limited quantity max net quantity (IATA)	: 0.5L
PCA packing instructions (IATA)	: 851
PCA max net quantity (IATA)	: 1L
CAO packing instructions (IATA)	: 855
CAO max net quantity (IATA)	: 30L
ERG code (IATA)	: 8L

- Rail transport

Classification code (RID)	: C1
Limited quantities (RID)	: 1L
Excepted quantities (RID)	: E2
Packing instructions (RID)	: P001, IBC02
Mixed packing provisions (RID)	: MP15
Portable tank and bulk container instructions (RID)	: T8
Portable tank and bulk container special provisions (RID)	: TP2
Tank codes for RID tanks (RID)	: L4BN
Transport category (RID)	: 2
Colis express (express parcels) (RID)	: CE6
Hazard identification number (RID)	: 80
Carriage prohibited (RID)	: No

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

15.1.1. EU-Regulations

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Contains no substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : sulphuric acid ... % is listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
R35	Causes severe burns
C	Corrosive

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product