

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product Name : rheumajet ASO
Product code : 3000-7010

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
3200-3444	Latex Reagent	Not classified	2 x 2.5 mL
3200-2588	Positive Control	Not classified	1 x 1.5 mL
3200-2478	Negative Control	Not classified	1 x 1.5 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 453/2010 of 20 May 2010 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 : Latex Reagent
Product code : 3200-3444
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

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 : 8.5% 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.

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 Regulation (EC) No. 1272/2008 [CLP]
Bronidox L Cognis	(CAS No) 30007-47-7 (EC no) 250-001-7	0,108	Skin Corr. 1B, H314 Aquatic Chronic 2, H411

Latex Reagent

Safety Data Sheet

according to Regulation (EC) No. 453/2010

sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
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Full text of H-phrases: 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.

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.

Latex Reagent

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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
Appearance	: Suspension.
Colour	: White.
Odour	: Odourless.
Odour threshold	: No data available
pH	: No data available
pH solution	: ≈ 7 (6,8 - 7,2)
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

Latex Reagent

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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	: 1,005 g/ml
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.

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

Bronidox L Cognis (30007-47-7)

LD50 oral rat	> 2000 - 5000 mg/kg
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sodium azide (26628-22-8)

LD50 oral rat	27 mg/kg
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LD50 dermal rat	50 mg/kg
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LD50 dermal rabbit	20 mg/kg
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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

Latex Reagent

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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

Bronidox L Cognis (30007-47-7)	
LC50 fish 1	≈ 5 (1 - 10) mg/l
EC50 other aquatic organisms 1	≈ 5 (1 - 10) mg/l

sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2 mg/l (96 h)

12.2. Persistence and degradability

Latex Reagent	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Latex Reagent	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Latex Reagent	
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

Latex Reagent

Safety Data Sheet

according to Regulation (EC) No. 453/2010

- 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 : Bovine Serum Albumine (BSA), fraction V is listed

SZW-lijst van mutagene stoffen : Bovine Serum Albumine (BSA), fraction V is 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 H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
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
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
H300	Fatal if swallowed
H314	Causes severe skin burns and eye damage
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 : Positive Control
Product code : 3200-2588
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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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

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 : 35% 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 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

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).

Positive Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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, 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.

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.

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.

Positive Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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	: 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	: 1,006 g/ml
Solubility	: Completely soluble.
Log Pow	: No data available

Positive Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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
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

Positive Control

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

Positive Control

Bioaccumulative potential	Not established.
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Positive Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Positive Control

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)

Positive Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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.

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 : 3200-2478
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

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 : 5.4% 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.

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 Regulation (EC) No. 1272/2008 [CLP]
sodium azide	(CAS No) 26628-22-8 (EC no) 247-852-1 (EC index no) 011-004-00-7	< 0,1	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Negative Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Full text of H-phrases: 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.

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.

Negative Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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 : 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

Negative Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Relative density	: No data available
Density	: 1,005 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

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

Negative Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

sodium azide (26628-22-8)	
EC50 Daphnia 1	4,2 mg/l (96 h)

12.2. Persistence and degradability

Negative Control

Persistence and degradability : Not established.

12.3. Bioaccumulative potential

Negative Control

Bioaccumulative potential : Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Negative Control

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

Negative Control

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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
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15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)
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15.2. Chemical safety assessment

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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 H- and EUH-statements:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
H300	Fatal if swallowed
H400	Very toxic to aquatic life
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