

Safety Data Sheet
according to Regulation (EC) No. 1907/2006

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IBL-America ELISA

Product identifier

Product Name: ELISA Immunoassay IgA / IgG / IgM

Product No.: IB05xxx

Composition

Test Components

Article No.	Article Name	Abbreviation
BP xxxx A/G/M	Break apart microtiter test strips each with eight antigen coated single wells, 12 pieces	MTP

B xxxx P A/G/M F	Standard serum (ready-to-use), 2 x 2 ml	STD
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or

B xxxx P A/G/M F	Positive control serum (ready-to-use), 2 ml	POS
B xxxx C A/G/M F	Cut off serum (ready-to-use), 2 x 2 ml	C/O

B xxxx N A/G/M F	Negative control serum (ready-to-use), 2 ml	NEG
KIG A/G/M R + / ++ / +++	Anti-human IgA, IgG or IgM conjugate (ready-to-use), 13 ml	APC
B232	Washing solution concentrate (sufficient for 1000 ml), 33,3 ml	WASH
B231 (-S1 / -S2 / -S3)	Dilution buffer, 2 x 50 ml	DILB (S1 / S2 / S3)
B235	Stopping solution, 15 ml	STOP
B236	Substrate (ready-to-use), 13 ml	pNPP
	Quality control certificate with standard curve and evaluation table	INFO

Attachment

Safety data sheets for test components

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

1.1 Product identifier

Product name: Breakable pre-coated microtiter strips with 8 individual wells

Product No.: AP xxxx, BP xxxx A/G/M

Abbreviation: MTP

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

Identified uses: *In-vitro* diagnostic or component

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Tel. 0049 (0) 931 – 30 45 0

Fax 0049 (0) 931 – 30 45 100

E-Mail dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center 0049 (0) 228 – 19 240 (German and English)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

2.2 Label elements

This product does not need to be labelled in accordance to EC directives or respective national laws.

2.3 Other hazards

This product is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

This product is not classified as dangerous according to Directives 67/548/EEC and 1999/45/EC and Regulation 1272/2008/EC.

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing. Consult physician if feeling unwell.

After eye contact: After initial flushing, remove any contact lenses and continue flushing. Continue irrigation until medical attention can be obtained.

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After swallowing: Do not induce vomiting. Provided the victim is conscious, wash out mouth with water and give water to drink.

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

No information available.

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

No information available.

SECTION 5: Firefighting measures

5.1 **Extinguishing media**

Suitable extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media

None known.

5.2 **Special hazards arising from the substance or measure**

Not combustible. Ambient fire may liberate hazardous vapours.

5.3 **Advice for firefighters**

Special protective equipment for firefighters

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact. Wear suitable protective clothing.

SECTION 6: Accidental release measures

6.1 **Personal precautions, protective equipment and emergency procedures**

6.1.1 **Advice for non-emergency personnel**

Do not breathe vapours, aerosols. Evacuate the danger area, follow emergency procedures, consult an expert.

6.1.2 **Advice for emergency responders**

Protective equipment see section 8.

6.2 **Environmental precautions**

No special precautionary measures necessary.

6.3 **Methods and materials for containment and cleaning up**

Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Dispose of via a licensed waste disposal contractor.

6.4 **Reference to other sections**

Indications about waste treatment see section 13.

SECTION 7: Handling and storage

7.1 **Precautions for safe handling**

7.1.1 **Advice on safe handling**

Put on appropriate personal protective equipment (see section 8).

7.1.2 **Hygiene measures**

Remove contaminated clothing. Wash hands and face at the end of the working period.

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7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Do not store in unlabeled containers.

Store at +2 °C to +25 °C.

7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Not indicated.

8.2 Exposure controls

8.2.1 Engineering measures

No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

8.2.2.1 Eye/face protection

Safety glasses.

8.2.2.2 Skin protection

Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Other protective equipment

Protective clothing.

8.2.2.3 Respiratory protection

Not indicated.

8.2.3 Environmental exposure controls

No special precautionary measures necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid
Colour	colourless
Odour	odourless
Odour Treshold	not applicable
pH	not applicable
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.

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Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	No information available.
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (i.e. room temperature).

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

No information available.

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

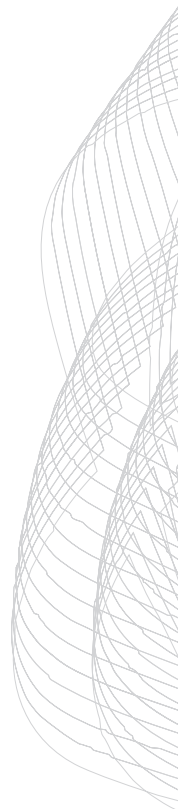
No information available.

Eye irritation

No information available.

Sensitization

No information available.



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Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity – single exposure

No information available.

Specific target organ toxicity – repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

SECTION 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT- and vPvB-assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

No information available.

SECTION 13: Disposal considerations

Waste treatment methods

Residual product should be disposed in accordance to EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste.

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SECTION 14: Transport information

14.1	UN-number	Not applicable.
14.2	Proper shipping name	Not applicable.
14.3	Class	Not applicable.
14.4	Packing group	Not applicable.
14.5	Environmentally hazardous	Not applicable.
14.6	Special precautions for user	Not applicable.
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

EC legislation None known.

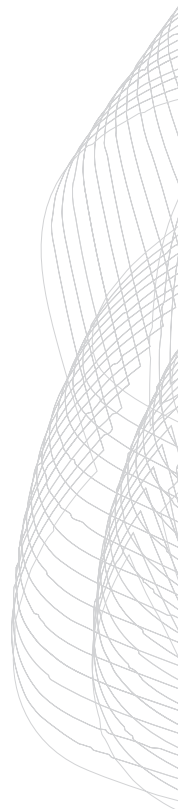
National legislation None known.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.



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

1.1 Product identifier

Product name: Control sera and SERION ELISA *control*

Product No: B xxxx P A/G/M F; B xxxx N A/G/M F; B xxxx C A/G/M F
BC xxxx A/G/M; C xxxx A/G/M

Abbreviation: STD, NEG, POS, C/O, SERION ELISA *control*

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

Identified uses: *In-vitro* diagnostic or component

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Tel. 0049 (0) 931 – 30 45 0

Fax 0049 (0) 931 – 30 45 100

E-Mail dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center 0049 (0) 228 – 19 240 (German and English)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

2.2 Label elements

This product does not need to be labelled in accordance to EC directives or respective national laws.

2.3 Other hazards

This product contains material of human origin; potentially infectious.

This product is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

SODIUM AZIDE

EC-No: 247-852-1; EINECS Annex I: 011-004-00-7; CAS-No. 26628-22-8

Concentration: < 0,1 % w/w

Classification (67/548/EEC or 1999/45/EC):

T+; R28-R32 • N; R50/53

Classification (Regulation (EC) No. 1272/2008):

Acute Tox. 2; H300 • Aquatic Acute 1; H400 • Aquatic Chronic 1; H410

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SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.
After skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing. Use skin disinfectant. Consult physician.
After eye contact: After initial flushing, remove any contact lenses and continue flushing. Continue irrigation until medical attention can be obtained.
After swallowing: Given the victim is conscious, induce vomiting. Rinse mouth and make victim drink water (two glasses at most). Immediately consult physician.

4.2 Most important symptoms and effects, both acute and delayed

Unconsciousness, dizziness, headache, nausea, vomiting, CNS symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or measure

Not combustible. Potential formation of toxic pyrolysis products. Nitrogen oxides (NO_x).

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

6.1.2 Advice for emergency responders

Protective equipment see section 8.

6.2 Environmental precautions

Do not empty into drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Observe label precautions.

7.1.2 Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in original container. Store at +2°C to +25°C.

7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

SODIUM AZIDE

AGW (Germany)

IOELV (EC)

	0,2 mg/m ³	2(l);DFG, EU
Short term:	0,3 mg/m ³	
Long term:	0,1 mg/m ³	
Skin		

8.2 Exposure controls

8.2.1 Engineering measures

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual protection measures

Do not eat, drink or smoke during working periods. Thoroughly wash hands after working periods.

8.2.2.1 Eye/face protection

Tightly fitting safety goggles.

8.2.2.2 Skin protection

Hand protection

Glove material e.g. Nitrile rubber or Butyl rubber.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Use of preventive skin care measures is recommended.

Other protective equipment

Protective clothing.

8.2.2.3 Respiratory protection

Not required.

8.2.3 Environmental exposure controls

Do not empty into drains.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	odourless
Odour Treshold	not applicable
pH	No information available.
Melting point	0 °C
Boiling point	100 °C
Flash point	not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,0 g/cm ³ at 20 °C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	not applicable
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

No further information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Contact with acids may liberate toxic gas.
Potential formation of nitrogen oxides (NO_x).

10.4 Conditions to avoid

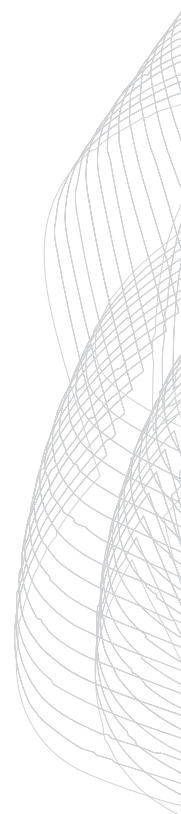
No information available.

10.5 Incompatible materials

Acids, heavy metals.

10.6 Hazardous decomposition products

Nitrogen oxides (see section 10.3).



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: headache, nausea, shock ^[1]

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

May cause skin irritation. May be harmful if absorbed through skin.

Eye irritation

May cause eye irritation.

Sensitisation

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure

No information available.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

^[1] Richardson et al. *J. Clin. Pathol.* **28** (1975), 350.

11.2 Further information

Quantitative data on the toxicity of this product are not available. This product contains human sourced materials. Although tested negative for anti-HIV antibodies, HBs-Ag (Hepatitis B-Virus-surface antigen) and anti-HCV antibodies, this product should be treated as being potentially infectious.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

Components

Sodium Azide (solid substance):

Acute oral toxicity

LD50 rat: 27 mg/kg

Acute dermal toxicity

LD50 rabbit: 20 mg/kg

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SECTION 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

Discharge into the environment must be avoided.

Components

Sodium Azide (solid substance):

Toxicity to fish

LC50 *Lepomis macrochirus*: 0,7 mg/l; 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia pulex*: 4,2 mg/l; 48 h

Biodegradability

The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulation

Bioaccumulation is unlikely.

SECTION 13: Disposal considerations

Waste treatment methods

Residual product should be disposed in accordance to EC and national directives, e.g. 2008/98/EG.

SECTION 14: Transport information

14.1	UN-number	Not applicable.
14.2	Proper shipping name	Not applicable.
14.3	Class	Not applicable.
14.4	Packing group	Not applicable.
14.5	Environmentally hazardous	Not applicable.
14.6	Special precautions for user	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code	Not applicable.

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SECTION 15: Regulatory information

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

EU regulations

Major Accident Hazard Legislation 96/82/EC:

Directive 96/82/EC does not apply

Occupational restrictions:

Take note of Dir 94/33/EC on the protection of young people at work.

National legislation

None known.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H-Statements and R-phrases referred to under section 3.2:

R28 Very toxic if swallowed

R32 Contact with acids liberates very toxic gas

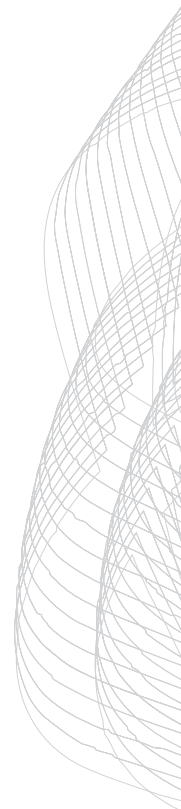
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

H300 Fatal if swallowed

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.



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

1.1 Product identifier

Product name: Wash solution SERION ELISA *classic*,
Dilution buffer SERION ELISA *classic*
Product No: B232, B231, B231-S1, B231-S2, B231-S3
Abbreviation: WASH, DILB, DILBS1, DILBS2, DILBS3

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

Identified uses: *In-vitro* diagnostic or component

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH
Friedrich-Bergius-Ring 19
97076 Würzburg
Germany
Tel. 0049 (0) 931 – 30 45 0
Fax 0049 (0) 931 – 30 45 100
E-Mail dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)
Poison Control Center 0049 (0) 228 – 19 240 (German and English)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

2.2 Label elements

This product does not need to be labelled in accordance to EC directives or respective national laws.

2.3 Other hazards

This product is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

SODIUM AZIDE
EC-No: 247-852-1; EINECS Annex I: 011-004-00-7; CAS-No. 26628-22-8
Concentration: < 0,1 % w/w

Classification (67/548/EEC or 1999/45/EC):

T+; R28-R32 • N; R50/53

Classification (Regulation (EC) No. 1272/2008):

Acute Tox. 2; H300 • Aquatic Acute 1; H400 • Aquatic Chronic 1; H410

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SECTION 4: First aid measures

4.1 Description of first aid measures

- After inhalation: Fresh air. Consult physician if feeling unwell.
- After skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing. Consult physician if needed.
- After eye contact: After initial flushing, remove any contact lenses and continue flushing. Continue irrigation until medical attention can be obtained.
- After swallowing: Given the victim is conscious, induce vomiting. Rinse mouth and make victim drink water (two glasses at most). Immediately consult physician.

4.2 Most important symptoms and effects, both acute and delayed

Unconsciousness, dizziness, headache, nausea, vomiting, CNS symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or measure

Not combustible. Potential formation of toxic pyrolysis products. Nitrogen oxides (NO_x).

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

6.1.2 Advice for emergency responders

Protective equipment see section 8.

6.2 Environmental precautions

Do not empty into drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Observe label precautions.

7.1.2 Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in original container. Store at +2°C to +25°C.

7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

SODIUM AZIDE

AGW (Germany)

IOELV (EC)

Short term:

0,2 mg/m³

2(l);DFG, EU

Long term:

0,1 mg/m³

Skin

8.2 Exposure controls

8.2.1 Engineering measures

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual protection measures

Do not eat, drink or smoke during working periods. Thoroughly wash hands after working periods.

8.2.2.1 Eye/face protection

Tightly fitting safety goggles.

8.2.2.2 Skin protection

Hand protection

Glove material e.g. Nitrile rubber or Butyl rubber.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Other protective equipment

Protective clothing.

8.2.2.3 Respiratory protection

Not required.

8.2.3 Environmental exposure controls

Do not empty into drains.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	odourless
Odour Treshold	not applicable
pH	No information available.
Melting point	0 °C
Boiling point	100 °C
Flash point	not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,0 g/cm ³ at 20 °C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	not applicable
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

No further information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Contact with acids may liberate toxic gas.
Potential formation of nitrogen oxides (NO_x).

10.4 Conditions to avoid

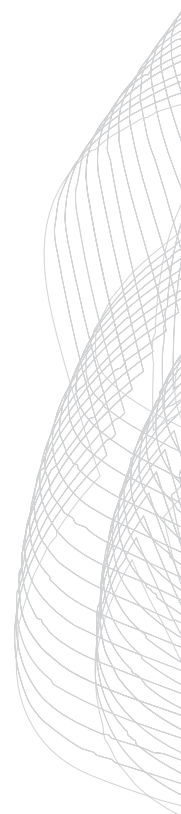
No information available.

10.5 Incompatible materials

Acids, heavy metals.

10.6 Hazardous decomposition products

Nitrogen oxides (see section 10.3).



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: headache, nausea, shock ^[1]

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

May cause skin irritation. May be harmful if absorbed through skin.

Eye irritation

May cause eye irritation.

Sensitisation

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure

No information available.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

^[1] Richardson et al. *J. Clin. Pathol.* **28** (1975), 350.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

Components

Sodium Azide (solid substance):

Acute oral toxicity

LD50 rat: 27 mg/kg

Acute dermal toxicity

LD50 rabbit: 20 mg/kg

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SECTION 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

Discharge into the environment must be avoided.

Components

Sodium Azide (solid substance):

Toxicity to fish

LC50 *Lepomis macrochirus*: 0,7 mg/l; 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia pulex*: 4,2 mg/l; 48 h

Biodegradability

The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulation

Bioaccumulation is unlikely.

SECTION 13: Disposal considerations

Waste treatment methods

Residual product should be disposed in accordance to EC and national directives, e.g. 2008/98/EG.

SECTION 14: Transport information

14.1	UN-number	Not applicable.
14.2	Proper shipping name	Not applicable.
14.3	Class	Not applicable.
14.4	Packing group	Not applicable.
14.5	Environmentally hazardous	Not applicable.
14.6	Special precautions for user	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code	Not applicable.

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SECTION 15: Regulatory information

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

EU regulations

Major Accident Hazard Legislation 96/82/EC:

Directive 96/82/EC does not apply

Occupational restrictions:

Take note of Dir 94/33/EC on the protection of young people at work.

National legislation

None known.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H-Statements and R-phrases referred to under section 3.2:

R28 Very toxic if swallowed

R32 Contact with acids liberates very toxic gas

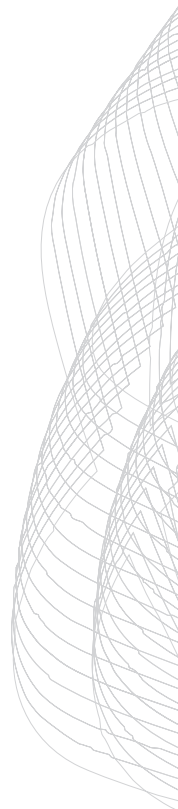
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

H300 Fatal if swallowed

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.



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

1.1 Product identifier

Product name: Conjugate solution
Product No: KIG A/G/M R +/+/+/+
Abbreviation: APC

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

Identified uses: *In-vitro* diagnostic or component

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH
Friedrich-Bergius-Ring 19
97076 Würzburg
Germany
Tel. 0049 (0) 931 – 30 45 0
Fax 0049 (0) 931 – 30 45 100
E-Mail dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)
Poison Control Center 0049 (0) 228 – 19 240 (German and English)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

2.2 Label elements

This product does not need to be labelled in accordance to EC directives or respective national laws.

2.3 Other hazards

This product is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

SODIUM AZIDE

EC-No: 247-852-1; EINECS Annex I: 011-004-00-7; CAS-No. 26628-22-8

Concentration: < 0,1 % w/w

Classification (67/548/EEC or 1999/45/EC):

T+; R28-R32 • N; R50/53

Classification (Regulation (EC) No. 1272/2008):

Acute Tox. 2; H300 • Aquatic Acute 1; H400 • Aquatic Chronic 1; H410

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SECTION 4: First aid measures

4.1 Description of first aid measures

- After inhalation: Fresh air. Consult physician if feeling unwell.
- After skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing. Consult physician if needed.
- After eye contact: After initial flushing, remove any contact lenses and continue flushing. Continue irrigation until medical attention can be obtained.
- After swallowing: Given the victim is conscious, induce vomiting. Rinse mouth and make victim drink water (two glasses at most). Immediately consult physician.

4.2 Most important symptoms and effects, both acute and delayed

Unconsciousness, dizziness, headache, nausea, vomiting, CNS symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or measure

Not combustible. Potential formation of toxic pyrolysis products. Nitrogen oxides (NO_x).

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

6.1.2 Advice for emergency responders

Protective equipment see section 8.

6.2 Environmental precautions

Do not empty into drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Observe label precautions.

7.1.2 Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in original container. Store at +2°C to +25°C.

7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

SODIUM AZIDE

AGW (Germany)

IOELV (EC)

	0,2 mg/m ³	2(l);DFG, EU
Short term:	0,3 mg/m ³	
Long term:	0,1 mg/m ³	
Skin		

8.2 Exposure controls

8.2.1 Engineering measures

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual protection measures

Do not eat, drink or smoke during working periods. Thoroughly wash hands after working periods.

8.2.2.1 Eye/face protection

Tightly fitting safety goggles.

8.2.2.2 Skin protection

Hand protection

Glove material e.g. Nitrile rubber or Butyl rubber.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Other protective equipment

Protective clothing.

8.2.2.3 Respiratory protection

Not required.

8.2.3 Environmental exposure controls

Do not empty into drains.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	odourless
Odour Treshold	not applicable
pH	No information available.
Melting point	0 °C
Boiling point	100 °C
Flash point	not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,0 g/cm ³ at 20 °C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	not applicable
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

No further information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Contact with acids may liberate toxic gas.
Potential formation of nitrogen oxides (NO_x).

10.4 Conditions to avoid

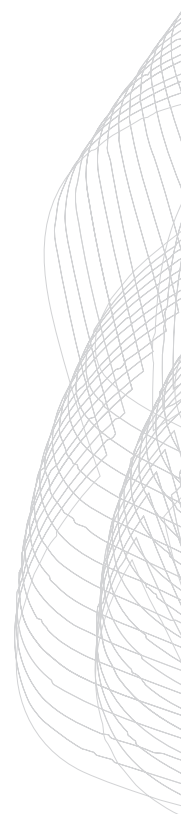
No information available.

10.5 Incompatible materials

Acids, heavy metals.

10.6 Hazardous decomposition products

Nitrogen oxides (see section 10.3).



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: headache, nausea, shock ^[1]

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

May cause skin irritation. May be harmful if absorbed through skin.

Eye irritation

May cause eye irritation.

Sensitisation

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure

No information available.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

^[1] Richardson et al. *J. Clin. Pathol.* **28** (1975), 350.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

Components

Sodium Azide (solid substance):

Acute oral toxicity

LD50 rat: 27 mg/kg

Acute dermal toxicity

LD50 rabbit: 20 mg/kg

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SECTION 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

Discharge into the environment must be avoided.

Components

Sodium Azide (solid substance):

Toxicity to fish

LC50 *Lepomis macrochirus*: 0,7 mg/l; 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia pulex*: 4,2 mg/l; 48 h

Biodegradability

The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulation

Bioaccumulation is unlikely.

SECTION 13: Disposal considerations

Waste treatment methods

Residual product should be disposed in accordance to EC and national directives, e.g. 2008/98/EG.

SECTION 14: Transport information

14.1	UN-number	Not applicable.
14.2	Proper shipping name	Not applicable.
14.3	Class	Not applicable.
14.4	Packing group	Not applicable.
14.5	Environmentally hazardous	Not applicable.
14.6	Special precautions for user	Not applicable.
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code	Not applicable.

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SECTION 15: Regulatory information

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

EU regulations

Major Accident Hazard Legislation 96/82/EC:

Directive 96/82/EC does not apply

Occupational restrictions:

Take note of Dir 94/33/EC on the protection of young people at work.

National legislation

None known.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H-Statements and R-phrases referred to under section 3.2:

R28 Very toxic if swallowed

R32 Contact with acids liberates very toxic gas

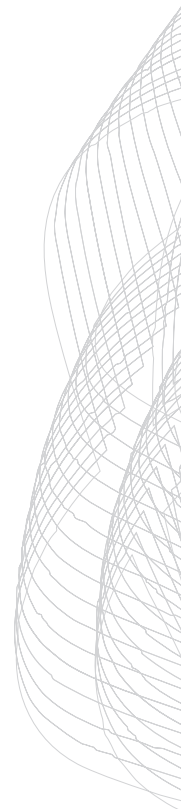
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

H300 Fatal if swallowed

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.



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

1.1 Product identifier

Product name: Substrate solution

Product No: B236

Abbreviation: pNPP

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

Identified uses: *In-vitro* diagnostic or component

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Tel. 0049 (0) 931 – 30 45 0

Fax 0049 (0) 931 – 30 45 100

E-Mail dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center 0049 (0) 228 – 19 240 (German and English)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

2.2 Label elements

This product does not need to be labelled in accordance to EC directives or respective national laws.

2.3 Other hazards

This product is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

SODIUM AZIDE

EC-No: 247-852-1; EINECS Annex I: 011-004-00-7;

CAS-No. 26628-22-8

Concentration: < 0,1 % w/w

Classification (67/548/EEC or 1999/45/EC):

T+; R28-R32 • N; R50/53

Classification (Regulation (EC) No. 1272/2008):

Acute Tox. 2; H300 • Aquatic Acute 1; H400 • Aquatic Chronic 1; H410

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TRIS(HYDROXYMETHYL)AMINOMETHANE

EC-No: 201-064-4

CAS-No. 77-86-1

Concentration: 6 % w/w

Classification (67/548/EEC or 1999/45/EC):

Xi; R36/38

Classification (Regulation (EC) No. 1272/2008):

Acute Eye Irrit. 2;H319 • Skin Irrit. 2;H315

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing. Consult physician if needed.

After eye contact: After initial flushing, remove any contact lenses and continue flushing. Continue irrigation until medical attention can be obtained.

After swallowing: Given the victim is conscious, induce vomiting. Rinse mouth and make victim drink water (two glasses at most). Immediately consult physician.

4.2 Most important symptoms and effects, both acute and delayed

Unconsciousness, dizziness, headache, nausea, vomiting, CNS symptoms.

Irritation of respiratory tract, eyes, skin and digestive tract.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or measure

Not combustible. Potential formation of toxic pyrolysis products. Nitrogen oxides (NO_x).

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation.

Evacuate the danger area, observe emergency procedures, consult an expert.

6.1.2 Advice for emergency responders

Protective equipment see section 8.

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6.2 Environmental precautions

Do not empty into drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Observe label precautions.

7.1.2 Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in original container. Store at +2°C to +25°C.

7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

SODIUM AZIDE

AGW (Germany)

IOELV (EC)

	0,2 mg/m ³	2(l);DFG, EU
Short term:	0,3 mg/m ³	
Long term:	0,1 mg/m ³	
Skin		

8.2 Exposure controls

8.2.1 Engineering measures

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual protection measures

Do not eat, drink or smoke during working periods. Thoroughly wash hands after working periods.

8.2.2.1 Eye/face protection

Tightly fitting safety goggles.

8.2.2.2 Skin protection

Hand protection

Glove material e.g. Nitrile rubber or Butyl rubber.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

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Other protective equipment

Protective clothing.

8.2.2.3 Respiratory protection

Not required.

8.2.3 Environmental exposure controls

Do not empty into drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	odourless
Odour Treshold	not applicable
pH	No information available.
Melting point	0 °C
Boiling point	100 °C
Flash point	not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,0 g/cm ³ at 20 °C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	not applicable
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

No further information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Contact with acids may liberate toxic gas.
Potential formation of nitrogen oxides (NO_x).

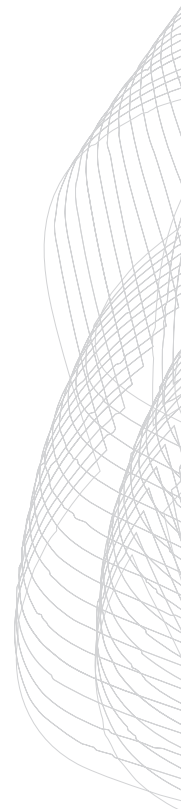
10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

Acids, heavy metals.

10.6 Hazardous decomposition products



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Nitrogen oxides (see section 10.3).

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: headache, nausea, shock ^[1]

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

May cause skin irritation. May be harmful if absorbed through skin.

Eye irritation

May cause eye irritation.

Sensitisation

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure

No information available.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

^[1] Richardson et al. *J. Clin. Pathol.* **28** (1975), 350.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

Components

Sodium Azide (solid substance):

Acute oral toxicity

LD50 rat: 27 mg/kg

Acute dermal toxicity

LD50 rabbit: 20 mg/kg

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Tris(hydroxymethyl)aminomethane

Acute oral toxicity

LD50 rat: 5900 mg/kg (RTECS)

SECTION 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

Discharge into the environment must be avoided.

Components

Sodium Azide (solid substance):

Toxicity to fish

LC50 *Lepomis macrochirus*: 0,7 mg/l; 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 *Daphnia pulex*: 4,2 mg/l; 48 h

Biodegradability

The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulation

Bioaccumulation is unlikely.

SECTION 13: Disposal considerations

Waste treatment methods

Residual product should be disposed in accordance to EC and national directives, e.g. 2008/98/EG.

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SECTION 14: Transport information

14.1	UN-number	Not applicable.
14.2	Proper shipping name	Not applicable.
14.3	Class	Not applicable.
14.4	Packing group	Not applicable.
14.5	Environmentally hazardous	Not applicable.
14.6	Special precautions for user	Not applicable.
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

EU regulations

Major Accident Hazard Legislation 96/82/EC:

Directive 96/82/EC does not apply

Occupational restrictions:

Take note of Dir 94/33/EC on the protection of young people at work.

National legislation

None known.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H-Statements and R-phrases referred to under section 3.2:

R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R36/38	Irritating to eyes and skin
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
H300	Fatal if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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

1.1 Product identifier

Product name: Stopplösung

Product No.: B235

Abbreviation: STOP

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

In-vitro diagnostic or component

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Tel. 0049 (0) 931 – 30 45 0

Fax 0049 (0) 931 – 30 45 100

E-Mail dialog@virion-serion.de

1.4 Emergency telephone number

Manufacturer 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center 0049 (0) 228 – 19 240 (German and English)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

This product is not classified in accordance to EC regulation No. 1272/2008.

Classification (67/548/EEC or 1999/45/EC)

This product is not classified in accordance to EC directives or respective national laws.

2.2 Label elements

This product does not need to be labelled in accordance to EC directives or respective national laws.

2.3 Other hazards

This product is not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

Sodium Hydroxide

EC-No: 215-185-5; EINECS: 011-002-00-6;

CAS-No: 1310-73-2

Concentration: < 0,5 % w/w

Classification (Regulation (EC) No. 1272/2008):

C ; R 35

Classification (67/548/EEC or 1999/45/EC):

Skin. Corr. 1A; H314

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SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.
After skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing. Consult physician if feeling unwell.
After eye contact: After initial flushing, remove any contact lenses and continue flushing. Continue irrigation until medical attention can be obtained.
After swallowing: Do not induce vomiting. Provided the victim is conscious, wash out mouth with water and give water to drink. Consult physician if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or measure

Not combustible. Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

6.1.2 Advice for emergency responders

Protective equipment see section 8.

6.2 Environmental precautions

No special precautionary measures necessary.

6.3 Methods and materials for containment and cleaning up

Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

Indications about waste treatment see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Observe label precautions.

7.1.2 Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Do not store in unlabeled containers.

Store at +2°C to +25°C.

7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Not indicated.

8.2 Exposure controls

8.2.1 Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See Section 7.1.

8.2.2 Individual protection measures

Do not eat, drink or smoke during working periods. Thoroughly wash hands after working periods.

8.2.2.1 Eye/face protection

Tightly fitting safety goggles.

8.2.2.2 Skin protection

Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Other protective equipment

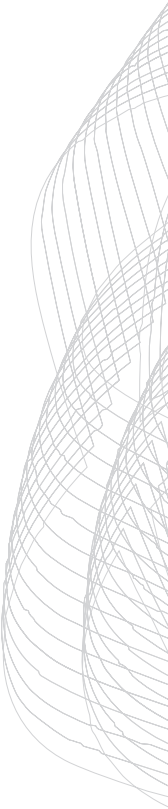
Protective clothing.

8.2.2.3 Respiratory protection

Not indicated.

8.2.3 Environmental exposure controls

No special precautionary measures necessary.



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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	odourless
Odour Treshold	not applicable
pH	ca. 13,7 at 20 °C
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,04 g/cm ³ at 20 °C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Corrosion	May be corrosive to metals.
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SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

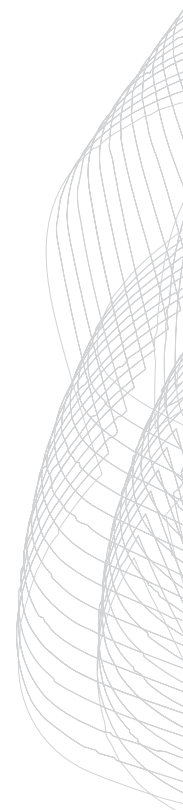
11.1 Information on toxicological effects

Mixture

Acute oral toxicity

No information available.

Acute inhalation toxicity



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No information available.

Acute dermal toxicity

No information available.

Skin irritation

No information available.

Eye irritation

No information available.

Sensitisation

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure

No information available.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

SECTION 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

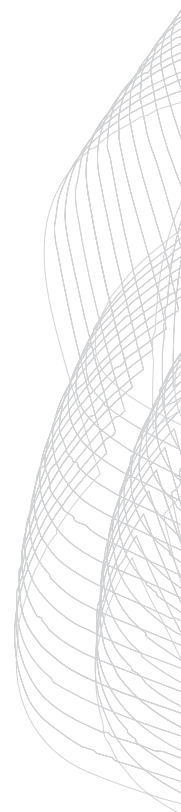
12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Additional ecological information

No information available.



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SECTION 13: Disposal considerations

Waste treatment methods

Residual product should be disposed in accordance to EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste.

SECTION 14: Transport information

14.1	UN-number	Not applicable.
14.2	Proper shipping name	Not applicable.
14.3	Class	Not applicable.
14.4	Packing group	Not applicable.
14.5	Environmentally hazardous	Not applicable.
14.6	Special precautions for user	Not applicable.
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

EC legislation None known.

National legislation None known.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H314 Causes severe skin burns and eye damage.

Full text of R-phrases referred to under sections 2 and 3

R35 Causes severe burns.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.



Manufactured for:

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