

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

1.1 Product identifier

Trade Name: Alfa 1 - Glicoproteína Ácida Reagent
 Article n°: 4080XXX
 MS: 80115310074

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

Reagent for *in-vitro* diagnostics in human samples
 For professional use only.

1.3 Manufacturer

Kovalent do Brasil Ltda.
 Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.
 Tel: +(55 21) 2623-1367
 e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number

Tel: +(55 21) 2623-1367 – Customer Service from 8am to 5pm
 0800 015 1414

In case of emergency – 24 hours service

0800-722-6001 – RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to ABNT NBR 14725.
 This mixture is classified as not hazardous.

2.2 Label elements

Labelling (GHS)

Hazard statements: Not applicable

Precautionary statements: Not applicable

2.3 Other hazards

Hazardous properties cannot be excluded

Sodium azide can form explosive azides when containing heavy metals such as copper or lead

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Mixture.

Description: Mixture of the substances listed below with harmless products.

Hazardous components:

Ingredient	Designation	Content	Classification
EC No. 247-852-1 CAS: 26628-22-8 Index Number: 011-004-00-7	Sodium azide	< 0.1%	Acute Tox Oral CAT 4; H302. Acute Aquatic Tox CAT 3; H412.

Additional information:

For the wording of the listed phrases refer to Section 16
 This reagent contains Sodium Azide as a preservative

4 First aid measures

4.1 Description of first aid measures

General information:	Remove contaminated clothing.
After inhalation:	Supply fresh air, consult doctor in case breathing problems develop. Unconscious: maintain adequate airway and respiration.
After skin contact:	Wash with soap and water. If symptoms persist, consult doctor.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor. Do not apply neutralizing agents.
After swallowing:	Rinse out mouth and then drink plenty of water. In case of persistent symptoms, consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO₂), extinguishing powder or water spray/fog. Fight larger fires with water spray/fog or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents: None

5.2 Special hazards arising from the substance or mixture

Special hazard caused by the material, its products of combustion or flue gases:
 Nitrogen oxides (Nox), Oxides of phosphorus (PxOy), Carbon monoxide (CO) and Carbon dioxide (CO₂).

5.3 Advice for firefighters

Protective equipment:	Put on breathing apparatus. Gas-tight suit.
Additional information:	Collect contaminated firefighting water separately. It must not enter drains.

6 Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

Person-related safety precautions: Wear protective clothing. Do not breathe vapors. Avoid skin and eye contact. See Section 8.

6.2 Environmental precautions

Measures for environmental protection: Do not allow to enter drainage system, surface or ground water. Discharge according to local regulations.

6.3 Methods and material for containment and cleaning up

Measures for cleaning/collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 Dispose of contaminated material as waste according to item 13.
 Clean contaminated surfaces with an excess of water.
 Wash clothing and equipment after handling

6.4 Reference to other sections

Refer additionally to section 8 and 13.

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7 Handling and storage

7.1 Precautions for safe handling

Information for safe handling:

- Observe normal to strict hygiene standards.
- Handle and open the container with care.
- Ensure good ventilation / exhaustion at the workplace.
- Do not inhale aerosols.
- Avoid prolonged or repeated skin contact.
- Avoid contact with eyes.
- Make sure that all applicable workplace limits are observed.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and containers: Observe all local and national regulations for storage of water polluting products.

Information about storage in one common storage facility: Not required

Further information about storage conditions:

- Keep container tightly sealed.
- Protect from heat and direct sunlight.
- Store in a cool place.
- Recommend storage temperature: 2 - 8 °C

7.3 Specific end use(s)

No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Additional information about design of technical systems: No further data; see item 7

Components with critical values that require monitoring at the workplace:

Designation	Type	Limit value
Sodium azide	WEL (Great Britain)	Short-term value: 0.3 mg/m ³
		Long-term value: 0.1 mg/m ³
	TLV (European Union)	Short-term value: 0.3 mg/m ³
		Long-term value: 0.1 mg/m ³
		Skin

Additional information: The list that were valid during the compilation were used as basis

8.2 Exposure controls

Personal protection equipment

General protective and hygienic measures:

- Keep away from foodstuffs, beverages and food.
- Do not inhale gases / fumes / aerosols.
- Avoid close or long-term contact with the skin.
- Avoid contact with the eyes.
- Wash hands during breaks and at the end of the work.

Breathing equipment: If all workplace limits are observed and good ventilation is ensured, no special precautions necessary

Protection on hands: Protective gloves. The glove material has to be impermeable and resistant to the product / the substance / the preparation.
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
 Check the permeability prior to each new use of the glove.

To avoid skin problems, reduce the wearing of gloves to the required minimum. Due to missing tests no recommendation to the glove material can be given for the product / the preparation / the chemical mixture

Material of gloves:	The selection of the suitable gloves does not only depend on the material but also on further marks of quality vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
Penetration time of the glove:	The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General information

Appearance:	Liquid
Colour:	Clear
Odour:	Odourless
Odour threshold:	No data available
pH value:	No data available

Change in condition

Melting point/ Melting range:	No data available
Boiling point/ Boiling range:	No data available
Evaporation rate:	No data available
Flash point/flash point range:	Not applicable
Self-inflammability:	Product is not self-igniting.
Danger of explosion:	Product is not explosive.
Density:	No data available
Solubility in / Miscibility with water:	Soluble

9.2 Other information

No data available

10 Stability and reactivity

10.1 Reactivity

Stable reactivity until expiry date if stored in recommended conditions.

10.2 Chemical stability

Stable until expiry date under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Thermal decomposition / conditions to be avoided: Sunlight / Heat

10.5 Incompatible materials

Materials to be avoided:

Strong oxidizing agents
 Strong acids
 Heavy metals

10.6 Hazardous decomposition products

Dangerous reactions may form very sensitive explosive metallic compounds.

Dangerous products of decomposition:

Nitrogen oxides (Nox), Oxides of phosphorus (PxOy)
 Carbon monoxide (CO) and Carbon dioxide (CO2)

11 Toxicological information

Acute toxicity (oral):

LD/LC50 values that are relevant for classification:

Sodium azide	Oral	LD50	27 mg/Kg (rat)
	Dermal	LD50	20 mg/Kg (rabbit)

Primary irritant effect on the skin:

No irritant effect.

Primary irritant effect on the eye:

No irritant effect.

Sensitization:

No sensitizing effect known.

Additional toxicological information:

The product is not object to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information

12.1 Toxicity

Ecotoxicological effects

Aquatic toxicity:

Sodium Azide	LC50/96 h	0,7 mg/L (Bluegill (<i>Lepomis macrochirus</i>))
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12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

Water hazard class 1

(self-assessment):

Slightly hazardous for water.

13 Disposal considerations

13.1 Waste treatment methods

Product:

Disposal must be made according to official regulations.

Package:	Disposal must be made according to official regulations.
Recommended cleaning agent:	Water, if necessary with cleaning agent.
Additional information:	Do not reuse empty containers.

14 Transport information

14.1 UN number or ID number
 ADR/RID, IMDG, IATA: Not applicable

14.2 UN proper shipping name
 ADR/RID, IMDG, IATA: Not restricted

14.3 Transport hazard class(es)
 ADR/RID, IMDG, IATA: Not applicable

14.4 Risk Number
 -

14.5 Packing group
 ADR/RID, IMDG, IATA: Not applicable

14.5 Environmental hazards
 Marine pollutant: No

14.6 Special precautions for user
 No dangerous goods in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

Wording of the H-phrases under paragraph 2 and 3:

Hazard statements:
 H302 = Harmful if swallowed
 H412 = Harmful to aquatic life with long lasting effects

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume.

Abbreviations and acronyms:

ABNT: Associação Brasileira de Normas Técnicas
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
 CAS: Chemical Abstracts Service
 CE: Conforme Européenne
 GHS: Globally Harmonized System
 IATA: International Air Transport Association
 IMDG Code: International Maritime Dangerous Goods Code

MS: Ministério da Saúde

NBR: Norma Brasileira

PBT: Persistent, bioaccumulative and toxic

RDC: Resolução da Diretoria Colegiada

RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica

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

vPvB: Very persistent and very bioaccumulative

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Reagent for *in-vitro* diagnostics in human samples
 For professional use only.

1.3 Manufacturer

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2.1 Classification of the substance or mixture

Classification according to ABNT NBR 14725.
 This mixture is classified as not hazardous.

2.2 Label elements

Labelling (GHS)

Hazard statements: Not applicable

Precautionary statements: Not applicable

2.3 Other hazards

Hazardous properties cannot be excluded

Sodium azide can form explosive azides when containing heavy metals such as copper or lead

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Mixture.

Description: Mixture of the substances listed below with harmless products.

Hazardous components:

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EC No. 247-852-1 CAS: 26628-22-8 Index Number: 011-004-00-7	Sodium azide	< 0.1%	Acute Tox Oral CAT 4; H302. Acute Aquatic Tox CAT 3; H412.

Additional information:

For the wording of the listed phrases refer to Section 16
 This reagent contains Sodium Azide as a preservative

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4.1 Description of first aid measures

General information:	Remove contaminated clothing.
After inhalation:	Supply fresh air, consult doctor in case breathing problems develop. Unconscious: maintain adequate airway and respiration.
After skin contact:	Wash with soap and water. If symptoms persist, consult doctor.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor. Do not apply neutralizing agents.
After swallowing:	Rinse out mouth and then drink plenty of water. In case of persistent symptoms, consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO₂), extinguishing powder or water spray/fog. Fight larger fires with water spray/fog or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents: None

5.2 Special hazards arising from the substance or mixture

Special hazard caused by the material, its products of combustion or flue gases:
 Nitrogen oxides (Nox), Oxides of phosphorus (PxOy), Carbon monoxide (CO) and Carbon dioxide (CO₂).

5.3 Advice for firefighters

Protective equipment:	Put on breathing apparatus. Gas-tight suit.
Additional information:	Collect contaminated firefighting water separately. It must not enter drains.

6 Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures

Person-related safety precautions: Wear protective clothing. Do not breathe vapors. Avoid skin and eye contact. See Section 8.

6.2 Environmental precautions

Measures for environmental protection: Do not allow to enter drainage system, surface or ground water. Discharge according to local regulations.

6.3 Methods and material for containment and cleaning up

Measures for cleaning/collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
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- Handle and open the container with care.
- Ensure good ventilation / exhaustion at the workplace.
- Do not inhale aerosols.
- Avoid prolonged or repeated skin contact.
- Avoid contact with eyes.
- Make sure that all applicable workplace limits are observed.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and containers: Observe all local and national regulations for storage of water polluting products.

Information about storage in one common storage facility: Not required

Further information about storage conditions:

- Keep container tightly sealed.
- Protect from heat and direct sunlight.
- Store in a cool place.
- Recommend storage temperature: 2 - 8 °C

7.3 Specific end use(s)

No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Additional information about design of technical systems: No further data; see item 7

Components with critical values that require monitoring at the workplace:

Designation	Type	Limit value
Sodium azide	WEL (Great Britain)	Short-term value: 0.3 mg/m ³
		Long-term value: 0.1 mg/m ³
	TLV (European Union)	Short-term value: 0.3 mg/m ³
		Long-term value: 0.1 mg/m ³
		Skin

Additional information: The list that were valid during the compilation were used as basis

8.2 Exposure controls

Personal protection equipment

General protective and hygienic measures:

- Keep away from foodstuffs, beverages and food.
- Do not inhale gases / fumes / aerosols.
- Avoid close or long-term contact with the skin.
- Avoid contact with the eyes.
- Wash hands during breaks and at the end of the work.

Breathing equipment: If all workplace limits are observed and good ventilation is ensured, no special precautions necessary

Protection on hands: Protective gloves. The glove material has to be impermeable and resistant to the product / the substance / the preparation.
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
 Check the permeability prior to each new use of the glove.

To avoid skin problems, reduce the wearing of gloves to the required minimum. Due to missing tests no recommendation to the glove material can be given for the product / the preparation / the chemical mixture

Material of gloves: The selection of the suitable gloves does not only depend on the material but also on further marks of quality vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of the glove: The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General information

Appearance:	Liquid
Colour:	Clear
Odour:	Odourless
Odour threshold:	No data available
pH value:	No data available

Change in condition

Melting point/ Melting range:	No data available
Boiling point/ Boiling range:	No data available
Evaporation rate:	No data available
Flash point/flash point range:	Not applicable
Self-inflammability:	Product is not self-igniting.
Danger of explosion:	Product is not explosive.
Density:	No data available
Solubility in / Miscibility with water:	Soluble

9.2 Other information

No data available

10 Stability and reactivity

10.1 Reactivity

Stable reactivity until expiry date if stored in recommended conditions.

10.2 Chemical stability

Stable until expiry date under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Thermal decomposition / conditions to be avoided: Sunlight / Heat

10.5 Incompatible materials

Materials to be avoided:

- Strong oxidizing agents
- Strong acids
- Heavy metals

10.6 Hazardous decomposition products

Dangerous reactions may form very sensitive explosive metallic compounds.

Dangerous products of decomposition: Nitrogen oxides (Nox), Oxides of phosphorus (PxOy)
 Carbon monoxide (CO) and Carbon dioxide (CO2)

11 Toxicological information

Acute toxicity (oral):

LD/LC50 values that are relevant for classification:

Sodium azide	Oral	LD50	27 mg/Kg (rat)
	Dermal	LD50	20 mg/Kg (rabbit)

Primary irritant effect on the skin: No irritant effect.

Primary irritant effect on the eye: No irritant effect.

Sensitization: No sensitizing effect known.

Additional toxicological information: The product is not object to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information

12.1 Toxicity

Ecotoxicological effects

Aquatic toxicity:	Sodium Azide	LC50/96 h	0,7 mg/L (Bluegill (<i>Lepomis macrochirus</i>))
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12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

Water hazard class 1
 (self-assessment): Slightly hazardous for water.

13 Disposal considerations

13.1 Waste treatment methods

Product: Disposal must be made according to official regulations.

Package:	Disposal must be made according to official regulations.
Recommended cleaning agent:	Water, if necessary with cleaning agent.
Additional information:	Do not reuse empty containers.

14 Transport information

14.1 UN number or ID number
 ADR/RID, IMDG, IATA: Not applicable

14.2 UN proper shipping name
 ADR/RID, IMDG, IATA: Not restricted

14.3 Transport hazard class(es)
 ADR/RID, IMDG, IATA: Not applicable

14.4 Risk Number
 -

14.5 Packing group
 ADR/RID, IMDG, IATA: Not applicable

14.5 Environmental hazards
 Marine pollutant: No

14.6 Special precautions for user
 No dangerous goods in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.
- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.
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16 Other information

Wording of the H-phrases under paragraph 2 and 3:

Hazard statements:
 H302 = Harmful if swallowed
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PBT: Persistent, bioaccumulative and toxic

RDC: Resolução da Diretoria Colegiada

RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica

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

vPvB: Very persistent and very bioaccumulative