

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

1.1 Product identifier

Trade Name: Alfa Amilase G7 Reagent R1

Article n°: 2080XXX

MS: 80115310093

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

No risks worthy of mention.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution.

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable EU-legislation.
Contains Sodium azide (0,95 g/L) as preservative.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. In case of respiratory difficulties seek medical attention.

Following skin contact: Change contaminated clothing.
Remove residues with water. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice.
Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters

Special protective equipment for firefighters: In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Do not breathe vapours. Wear appropriate protective equipment.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.

Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Do not breathe vapours. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light.

Hints on joint storage: Do not store together with: acids, alkalis.

Storage class: 12 = Non-combustible liquids

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7.3 Specific end use(s)

No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Provide adequate ventilation.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber. Breakthrough time: > 480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work. Do not breathe vapours. Do not eat, drink or smoke when using this product.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

9 Physical and chemical properties

Colour:	colourless, clear
Odour:	odourless
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive Limits:	No data available
Flash point/flash point range:	not combustible
Decomposition temperature	No data available
pH:	at 37 °C: 7,15
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available

Density:	at 20 °C: 1.009 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable
Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available
Additional information:	No data available

10 Stability and reactivity

10.1 Reactivity

Refer to 10.3.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reaction known.

10.4 Conditions to avoid

Protect against heat / sun rays.

10.5 Incompatible materials

Acids, alkalis.

10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

11 Toxicological information

Acute toxicity (oral):	Lack of data.
Acute toxicity (dermal):	Lack of data.
Acute toxicity (inhalative):	Lack of data.
Skin corrosion/irritation:	Lack of data.
Serious eye damage/irritation:	Lack of data.
Sensitisation to the respiratory tract:	Lack of data.
Skin sensitisation:	Lack of data.
Germ cell mutagenicity/Genotoxicity:	Lack of data.
Carcinogenicity:	Lack of data.
Reproductive toxicity:	Lack of data.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Lack of data.
Specific target organ toxicity (repeated exposure):	Lack of data.
Aspiration hazard:	Lack of data.

Endocrine disrupting properties: No data available

Other information: Contains Sodium azide (0.95 g/L):
After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

12 Ecological information

12.1 Toxicity

Water hazard class: 1 = Slightly hazardous to water

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

General information: Do not allow to enter into groundwater, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Special waste. Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA, ANTT: Not restricted

14.3 Transport hazard class(es)

ADR/RID: Not applicable

IMDG: Not applicable

IATA: Not applicable

ANTT: Not applicable

14.4 Risk Number

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14.5 Packing group

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.6 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to regulations.

Marine pollutant: No

14.7 Special precautions for user

No dangerous good 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

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 / National Standards Forum
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
 ANTT: Agência Nacional de Transporte Terrestre / National Agency of Transportation by Road
 AS/NZS: Australian Standards/New Zealand Standards
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 CNS: Central Nervous System
 DMEL: Derived minimal effect level
 DNEL: Derived no-effect level
 EC: European Community
 EN: European Standard
 EQ: Excepted quantities
 EU: European Union
 GHS: Globally Harmonized System
 IATA: International Air Transport Association
 IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
 IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
 IMDG Code: International Maritime Dangerous Goods Code
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 MS: Anvisa's Registry Code
 NBR: Brazilian technical ordinance
 OSHA: Occupational Safety and Health Administration
 pH: Potential of Hydrogen
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 RDC: Resolution from the Directory Board
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 TRGS: Technical Rules for Hazardous Substances
 UN: United Nations

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

1.1 Product identifier

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Article n°: 2080XXX

MS: 80115310093

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Reagent for *in-vitro* diagnostics in human samples

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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

No risks worthy of mention.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

3 Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization: Aqueous solution.

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable legislation.
Contains Sodium azide (0.95 g/L) as preservative.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. In case of respiratory difficulties seek medical attention.

Following skin contact: Change contaminated clothing.
Remove residues with water. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice.
Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters

Special protective equipment for firefighters: In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Wear appropriate protective equipment.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.

Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light.

Hints on joint storage: Do not store together with: acids, alkalis.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

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No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Provide adequate ventilation.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber. Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

Environmental exposure controls

Refer to "6.2 Environmental precautions".

9 Physical and chemical properties

Physical state at 20 °C and 101.3 kPa: liquid

Colour: yellowish, clear

Odour: odourless

Odour threshold: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flammability: No data available

Upper/lower flammability or explosive Limits: No data available

Flash point/flash point range: not combustible

Decomposition temperature: No data available

pH: at 37 °C: 7,15

Viscosity, kinematic: No data available

Water solubility: completely miscible

Partition coefficient: n-octanol/water: No data available

Vapour pressure: No data available

Density:	at 20 °C: 1.017 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable
Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available
Additional information:	No data available

10 Stability and reactivity

10.1 Reactivity

Refer to 10.3.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat / sun rays. Protect from frost.

10.5 Incompatible materials

Acids and alkalis.

10.6 Hazardous decomposition products

No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

11 Toxicological information

Acute toxicity (oral):	Lack of data.
Acute toxicity (dermal):	Lack of data.
Acute toxicity (inhalative):	Lack of data.
Skin corrosion/irritation:	Lack of data.
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Sensitisation to the respiratory tract:	Lack of data.
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Germ cell mutagenicity/Genotoxicity:	Lack of data.
Carcinogenicity:	Lack of data.
Reproductive toxicity:	Lack of data.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Lack of data.
Specific target organ toxicity (repeated exposure):	Lack of data.
Aspiration hazard:	Lack of data.

Endocrine disrupting properties: No data available

Other information: Contains Sodium azide (0.95 g/L):
After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

12 Ecological information

12.1 Toxicity

Water hazard class: 1 = Slightly hazardous to water

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

General information: Do not allow to enter groundwater, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Special waste. Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA, ANTT: Not restricted

14.3 Transport hazard class(es)

ADR/RID: Not applicable
IMDG: Not applicable
IATA: Not applicable
ANTT: Not applicable

14.4 Risk Number

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14.5 Packing group

ADR/RID, IMDG, IATA, ANTT: Not applicable

14.6 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to regulations
Marine pollutant: No

14.7 Special precautions for user

No dangerous good 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.
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